Haemonetics®
MCS®+ LN 9000
Platelet Protocols

Printed in U.S.A.
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June 2000
Part No. 39552, Rev. H

PROPRIETARY

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WARNING!

Buyer's Use of Products

Haemonetics Corporation warrants only the Haemonetics MCS®+ as supplied. When properly assembled, maintained and operated by a qualified operator, the MCS+ has the capacity of safely and adequately performing platelet collections.

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNING!

This manual provides certain basic information concerning the platelet protocols operation of the Haemonetics MCS®+ and is intended to be used in conjunction with and as a supplement to the training supplied by a Haemonetics Clinical Specialist or other qualified personnel. Departures or deviations from the procedures contained in this manual should not be made except in conformity with official changes made to the manual by Haemonetics Corporation. Other departures or deviations are at the operator's own risk.

Safe and effective use of Haemonetics products requires application of proper techniques of setup and operation, and accordingly, should be undertaken only by trained personnel.

Any Buyer that intends to use Haemonetics® products should:

- Read carefully the instructions supplied herewith.
- Read carefully the instructions in the MCS+ LN9000 Operator and Maintenance Manual.
- Secure training in the procedures to be used.
- Apply in vitro studies to verify the ability to use the products safely in vivo.

Information with respect to the availability of such training can be obtained by writing to Haemonetics Corporation, Attention: Customer Service, or contact your local account manager.

The uses to which the Haemonetics products may be applied, and the results obtained therefrom, shall be the sole responsibility of the Buyer. Haemonetics expressly disclaims responsibility for the use of the products by the Buyer.

INQUIRIES

Please direct any written inquiries to:

Haemonetics Corporation
400 Wood Road
Braintree, Massachusetts 02184, U.S.A.
(781) 848-7100

In the United States, telephone inquiries may be made by using the dedicated MCS+ Hotline: (800) 433-3431.

Haemonetics can be visited on the internet at www.haemonetics.com.

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GENERAL

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OVERVIEW

The following apheresis platelet collection options are available:

1. Single Donor Platelets (SDP). A customer-programmed apheresis platelet product is collected by the MCS+.
2. Platelets and Plasma (PLP). A customer-programmed apheresis platelet product and a customer-defined volume of concurrent plasma are collected by the MCS+.
3. Single Donor Platelets with Saline Replacement (SDPS). A customer-programmed apheresis platelet product is collected by the MCS+. The donor receives a preprogrammed volume of replacement fluid (saline) each cycle of the procedure.
4. Platelets and Plasma with Saline Replacement (PLPS). A customer-programmed apheresis platelet product and a customer-defined volume of concurrent plasma are collected by the MCS+. The donor receives a preprogrammed volume of replacement fluid (saline) each cycle of the procedure.

The SDP and SDPS protocols can also be used to collect Double Platelet Products. The MCS+ collects a customer-programmed apheresis platelet product that can be split into individual transfusable platelet products, each maintaining 5-day storage capability.

Note: The total content of the product must be greater than 6.0 x $10^{11}$for the collected product to constitute a double product. Following splitting of the product, each individual product must meet the criteria for a single donor platelet product as defined by the AABB (>3.0 x 10^{11} platelets).

Note: Depending on the disposable used, one or more leukocyte-reduced platelet products may be collected. Refer to the section on Leukocyte Management for further details.

Note: The volume of the product varies depending on the programmed yield of the product and donor dependent variables such as platelet precount. A platelet product with a yield between 3.0 x 10^{11} and 4.5 x 10^{11} is typically suspended in approximately 200 to 300 ml. A platelet product with a yield between 6.0 x 10^{11} and 8.0 x 10^{11} is typically suspended in approximately 350 to 450 ml.

SUPPLIES NEEDED

1. MCS+ Single Donor Platelets Disposable Set (List No. 994CF; List No. 994CF-CPP; List No. 994F or List No. 994)

Note: Platelet disposables with the designation "-CPP" contain CPP platelet storage bags. Platelet bags made of CPP material can each store up to 5.0 x 10^{11} platelets for five days with a maximum concentration of 2600 x 10^{6} platelets per ml.

Note: Platelet disposables without the designation "-CPP" contain CLX platelet storage bags. Platelet bags made of CLX can each store up to 3.5 x 10^{11} platelets for five days.

2. SDP/PLP Protocol Card
3. Venipuncture materials
4. Hemostats
5. ACD-A anticoagulant (500 ml) or larger
6. SDPS and PLPS only: 0.9% normal saline (500 ml) or larger

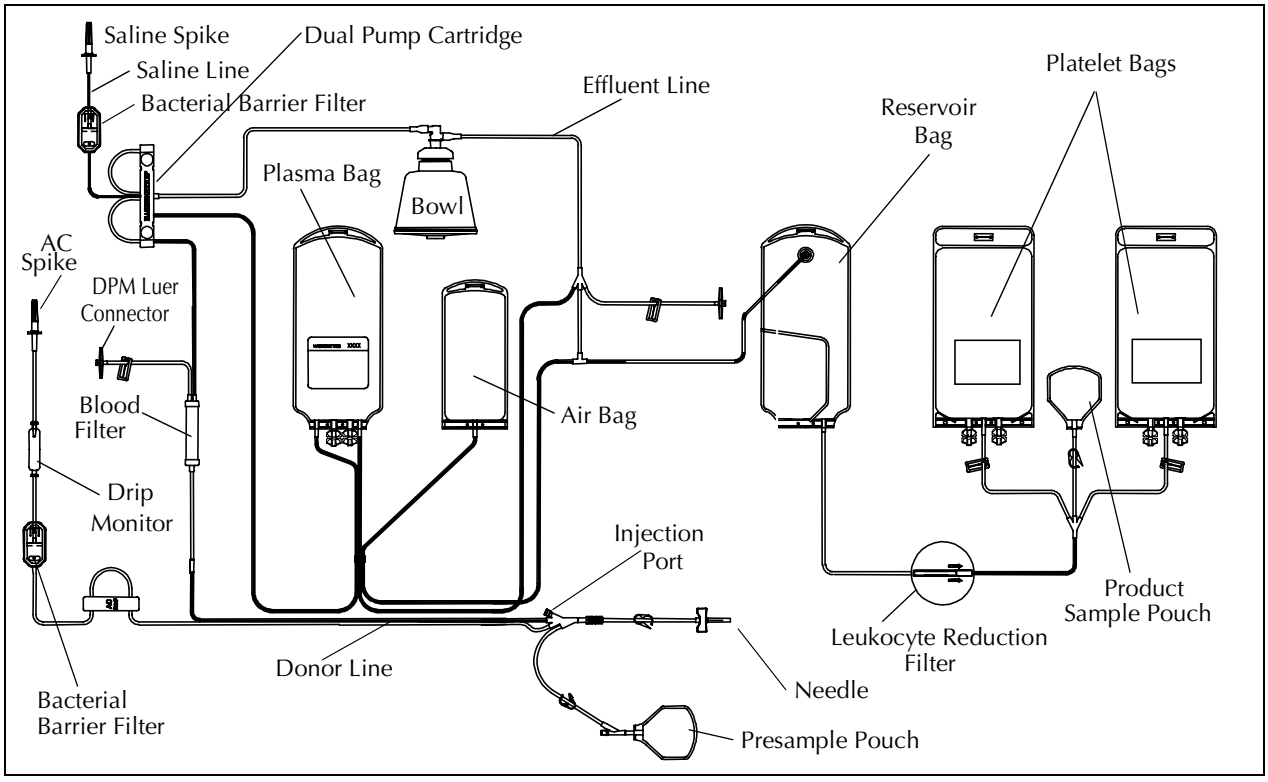


Figure 1, Platelet Disposable Set, List Number 994CF shown as example

The following warnings serve as general guidelines, and are applicable throughout operation of the MCS+, its disposables and handling of collected products:

Warning! Any action that may compromise the sterile fluid pathway of the disposable before hermetically sealing off the collected products, may affect the storage dating of the collected products. When the sterile fluid pathway has been compromised, the resulting platelet product must be transfused within 24 hours. If the resulting components are to be stored frozen, the dating is not affected.
Actions that may compromise the sterile fluid pathway include, but are not limited to:

- **Removal of the pre-attached needle**
- **Puncturing the injection port on the disposable**
- **Detaching products prior to hermetically sealing the products**
- **Leaks in the disposable**
- **Wetted SPM**
- **Violation of aseptic technique**
- **Inadequate preparation of the venipuncture site**

Warning! Biological Safety. Haemonetics recommends handling all biologically contaminated materials pursuant to those policies and procedures dictated by the institution's Exposure Control Plan.

Warning! Clean any spills immediately.

PREPARE THE MCS+

The MCS+ Platelet Protocol Card must be loaded into the protocol card port before the machine is powered on.

Note: When loading a protocol card, the performance of the equipment does not need to be revalidated unless the message, "Protocol Parameters Reset" is displayed or the loaded version of software has not been previously validated. If the message, "Protocol Parameters Reset" is displayed, ensure that all parameters in the HaemoCalculator and Modify screens are programmed to the site-preferred default settings if different from the Haemonetics default settings. The MCS+ will not allow the system to complete its self-test or initiate a procedure when the software on the protocol card contains erroneous information.

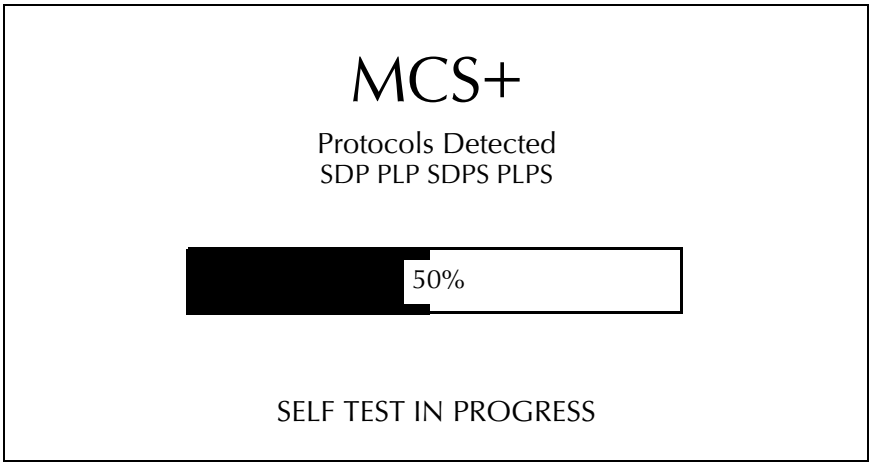
1. Open the cover of the MCS+.

2. Place the weigher arm in its fully extended position.
3. Turn the MCS+ on.

After the MCS+ is powered on, two diagnostic self-tests are performed. During this brief time nothing is displayed on the screen, but a tone is heard. If the self-test is unsuccessful, the tone will continue. The operator should power off the machine and contact Haemonetics Field Service.

After the MCS+ has performed the self-tests, a screen test is performed by illuminating the screen. Be sure that all pixels are lit. If any part of the screen is not illuminated, power off the machine and contact Haemonetics Field Service.

The power-up screen with the text, "HAEMONETICS CORPORATION MCS+" is displayed briefly. Next, the self-test screen is displayed. At this time a wide array of internal diagnostic tests are conducted to ensure that all systems are functioning properly. The following display shows a bar graph that indicates the percentage of tests complete. At this time, all electronic and computer components of the MCS+ are being tested. While the MCS+ conducts its internal diagnostics, do not move pumps or valves of the MCS+.



Note: If any of the internal diagnostic tests fail, a detailed description of the test failure is displayed. This message will give the operator further instructions depending on the nature of the test failure. The MCS+ will not allow the operator to continue with the procedure and the operator will have to power the MCS+ off.

Note: In the event that the MCS+ does not pass its self-test, follow the instructions provided in the help screen. In most cases the issue can be addressed by powering off and then on again. Call the Haemonetics Hotline if the problem persists.

On completion of the power-on tests, the MCS+ will prompt the operator to test the centrifuge cover lock by opening and closing the lock as directed.

After testing is complete, the following screen is shown.

SELECT PROTOCOL
Single Donor Platelets (SDP) Platelets and Plasma (PLP) **SDP with Saline Return (SDPS)** PLP with Saline Return (PLPS) REVISION x.x
Press DRAW to select protocol. Press MODIFY to change protocol. Press HELP for the HaemoUpdate Display.

The MODIFY key can be used to scroll through the menu and the DRAW key is used to select the protocol. Select the platelet protocol of choice. The following display will appear.

SDPS Installation
PLEASE INSTALL THE DISPOSABLE: Load the Bowl Close the Centrifuge Cover Snap the Pump Cartridge in Place Install the Tubing in the Line Sensor Install the System Pressure Monitor (SPM) Install the Donor Pressure Monitor (DPM)
Press HELP for More Information.

Note: Do not load the disposable until the above message is displayed.

Note: Hands should be free of dirt and/or lotion when handling the disposable to eliminate the chance of deposits collecting on the machine or disposable component surfaces. This helps to ensure that the performance of the Optic Sensors is not adversely affected.

Inspect the Disposable

1. Read the label on the disposable set to ensure it is the correct platelet disposable list number for the MCS+.
2. Confirm that the tub and cover of the disposable set have not been damaged during shipment or storage. Any damage could compromise the sterility of the disposable set. Do not use a damaged disposable.
3. Peel back the cover from the disposable tub and place the tub in the open lid of the MCS+ with the bowl upside down. The disposable tub is held firmly in place while you load the disposable onto the MCS+.

Note: The procedure should be initiated within 24 hours of removing the cover.

Note: Always inspect the disposable set as it is removed from the package. Be sure there are no kinks that might obstruct flow through the tubing.

Note: You can load the disposable onto the MCS+ without seeing the screen.

Load the Disposable

1. Extend both of the arms of the IV pole fully.
2. Open the Centrifuge Cover.
3. Remove the purple-striped saline line from the tub. Hang the saline line temporarily over the lower arm of the pole. This is the saline replacement line.
4. Remove the Latham bowl and the dual pump cartridge from the disposable tub. Place the bowl into the Centrifuge Well. Ensure that the centrifuge chuck holds the bowl securely in place. A beep sounds, and the text for loading the bowl disappears from the screen.
5. Close the Centrifuge Cover, ensuring that the effluent tubing is facing to the right of the MCS+ (clear tubing/low port) and that the tubing is not under the Centrifuge Cover. Tighten the Centrifuge Cover latch. A beep sounds, and the text for closing the Centrifuge Cover disappears from the screen.
6. Loop the tubing from the dual pump cartridge around the Blood and White Pumps. Snap the pump cartridge into place, ensuring that it locks into place. The text for snapping the pump cartridge in place disappears from the screen.

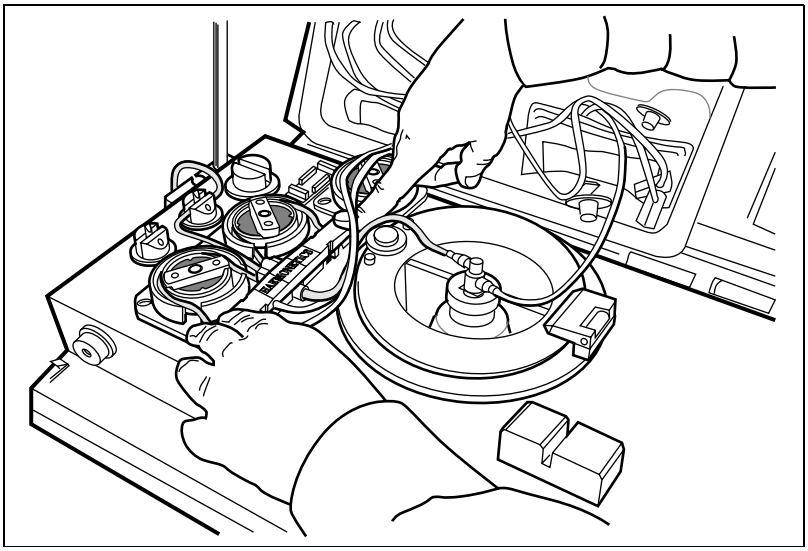


Figure 2, Installation of dual pump cartridge

7. Install the purple-striped saline tubing into the Purple Valve by flossing the tubing into the valve channel.

8. Remove the platelet bags. Hang the platelet bags with the ports up on the bag pins on the right side panel of the MCS+. Alternatively for convenience, the bags may be hung on the bag pins on the front panel of the MCS+ to the right of the weigher arm.

Note: When installing a disposable with a leukocyte filter (LN 994CF, 994CF-CPP or 994F), refer to the chapter on leukocyte management system for instructions on installing the collection bags and filter.

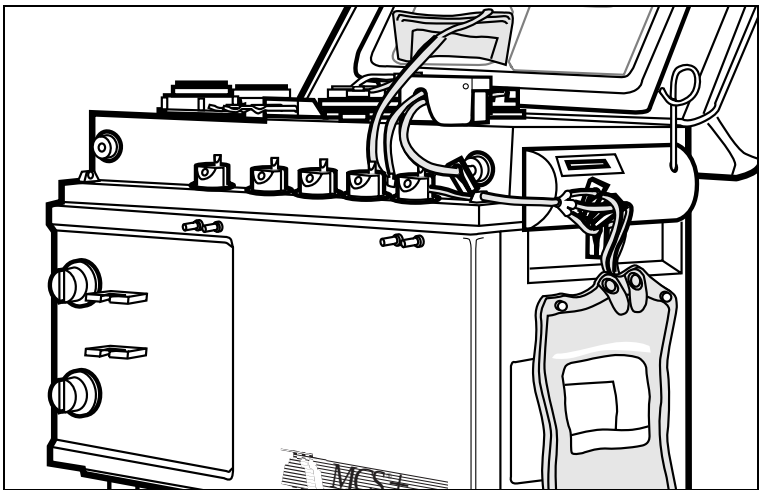


Figure 3, Installation of platelet bags

9. Close the red slide clamp on one of the platelet bags and the white clamp on the sample pouch.

Warning! The red slide clamp on one platelet bag must be unclamped throughout the procedure.

10. Remove the air bag and plasma bag from the tub. Hang the plasma bag, with the ports down, on the Weigher arm. Ensure that the plasma bag hangs freely.

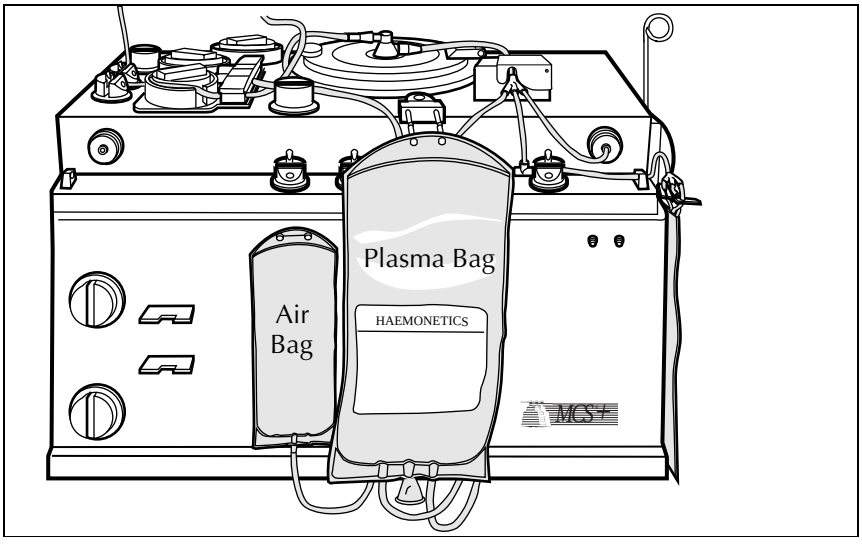


Figure 4, Installation of air and plasma bags

11. Hang the air bag with port down on the bag pins to the left of the weigher.
12. Floss the clear line sensor tubing through the Line Sensor. Floss the tubing until the text for loading the Line Sensor disappears from the screen.

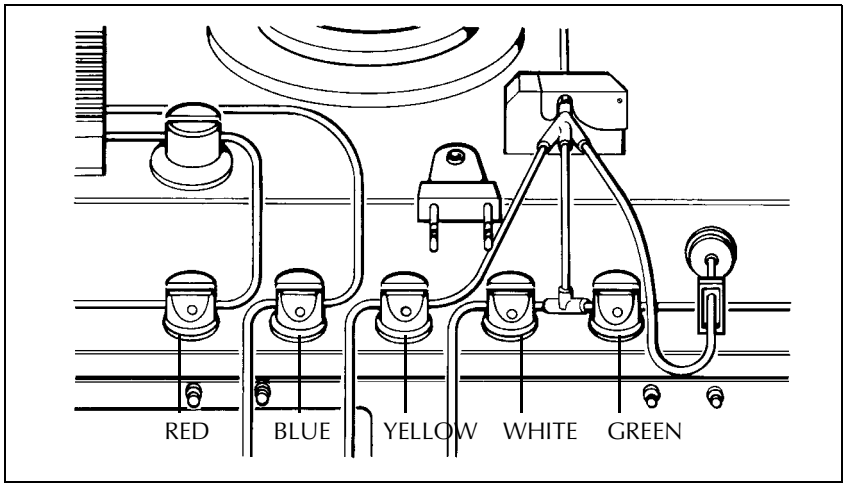


Figure 5, Correct Installation of Tubing

13. Connect the System Pressure Monitor (SPM) luer to the SPM port. Push the filtered luer inward onto the port until it goes no further and turn it about one-quarter turn. The text for installing the SPM disappears from the screen. Tug slightly. If the SPM luer comes off, it was not secure. Reconnect assuring secure installation.

Warning! Always be sure to push and turn the SPM filter onto the SPM port. Failure to do so may result in blood contacting the filter material. Once the SPM filter membrane has been wetted, the MCS+ will no longer be able to properly monitor pressure in the effluent side of the disposable set. The sterile pathway should be considered compromised.
A wetted SPM does not necessarily trigger an audible alarm. Therefore, Haemonetics recommends that the condition of the SPM be noted and recorded on ending the procedure.

14. Install the green-striped tubing into the Green Valve by flossing the tubing into the valve channel.
15. Install the white-striped tubing into the White Valve by flossing the tubing into the channel.
16. Install the yellow-striped tubing into the Yellow Valve by flossing the tubing into the valve channel.
17. Install the blue-striped tubing into the Blue Valve by flossing the tubing into the valve channel.

18. Remove the blood filter chamber from the disposable tub and place it in the filter housing located on the front of the MCS+.

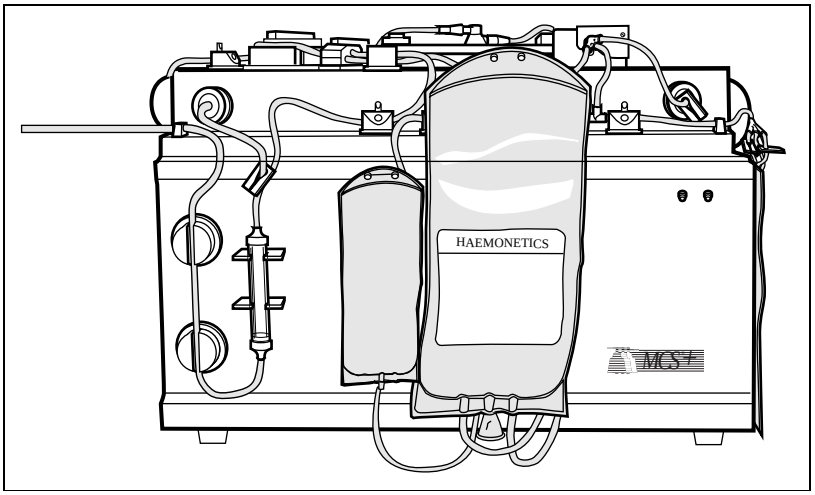


Figure 6, Installation of donor line

19. Install the red-striped tubing into the Blood Line Air Detector by flossing the tubing into the air detector channel.
20. Install the red-striped tubing into the Red Valve by flossing the tubing into the valve channel.
21. Install the clear tubing into the Donor Line Air Detector 1 and Donor Line Air Detector 2 by flossing the tubing into the two air detector channels.
22. Install the DPM filter on the DPM port. Push the filter firmly onto the port until it goes no further, and turn it about a quarter-turn. The text for installing the DPM will disappear from the screen. Tug slightly. If the DPM comes off, it was not secure. Reconnect assuring secure installation.

Warning! Always be sure to push and turn the DPM filter onto the DPM port. Failure to do so may result in blood contacting the filter material. Once the DPM filter membrane has been wetted, the MCS+ will no longer be able to properly monitor venous pressure. The procedure may continue, provided the operator monitors the venipuncture site. A wetted DPM does not result in a compromised fluid pathway.

23. Remove the donor needle assembly from the disposable tub and remove the paper tab. Confirm that the needle is firmly secured to the donor harness.
24. Remove the anticoagulant (AC) line and single pump cartridge from the disposable tub and remove the paper tab.

25. Loop the tubing in the single pump cartridge around the AC pump. Snap the pump cartridge into place.

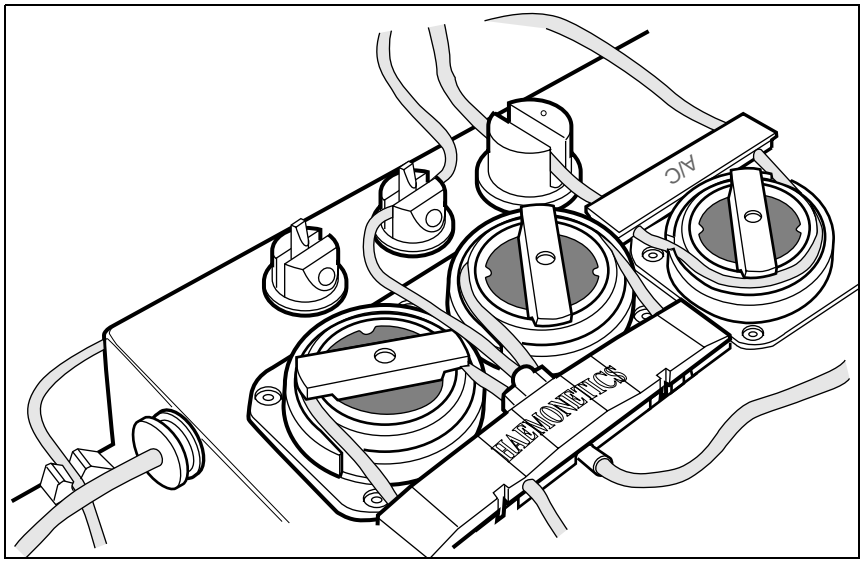


Figure 7, Installation of single pump cartridge

26. Install the AC tubing into the Anticoagulant Air Detector by flossing the tubing into the air detector channel.

Note: Do not load the drip monitor chamber until the pumps have been autoloaded.

27. Clamp the sample pouch near the needle line.

Warning! If the disposable includes an injection port: Use of this port compromises the sterile fluid pathway.

Remove the empty disposable tub from the lid of the machine. The following display appears. Check that the disposable has been loaded correctly.

SDPS	Installation
Please Confirm that: The Valves are Loaded The Pump Tubing is Looped The Bag is on the Weigher	
Press DRAW to Load the Pumps.	

Autoload the Pumps

The MCS+ is equipped with an automatic pump loading feature. To autoload the pumps, proceed as follows.

1. Check that the pump tubing is properly looped around the autoload guides (Anticoagulant, White, and Blood Pumps).
2. Press DRAW to load the pumps. The autoloading pump heads turn several times to load the tubing into the pumps.

SDPS	Installation
AUTOLOADING PUMPS	
Press STOP to Stop the Pumps.	

Prime the Disposable

To prime the system, proceed as follows.

Note: The AC line has clear tubing and leads to a separate drip chamber.

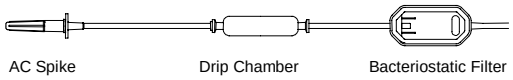


Figure 8, AC Spike Configuration

Note: The saline line has purple-striped tubing that leads to the dual pump cartridge.

Note: Once the pumps have been loaded, the MCS+ displays the following screen. Do not press PRIME until all items listed have been accomplished.

SDPS	Installation
Please Confirm that: The Sample Pouch Line is Clamped The Needle Line is Clamped The Anticoagulant is Spiked The Drip Monitor is Loaded The Saline Bag is Spiked	
Press PRIME to Prime the Disposable.	

1. Using aseptic technique, spike the AC bag with the anticoagulant spike. Hang the AC bag on the lower arm of the IV pole.

Warning! To ensure that the AC line is spiked onto the AC bag, follow the line visually to the Anticoagulant Pump.

2. Squeeze the drip chamber to fill about 1/8″ of AC in the drip chamber.

3. Install the drip chamber into the drip monitor housing so that it is seated against the bottom surface of the housing, as shown in Figure 9.

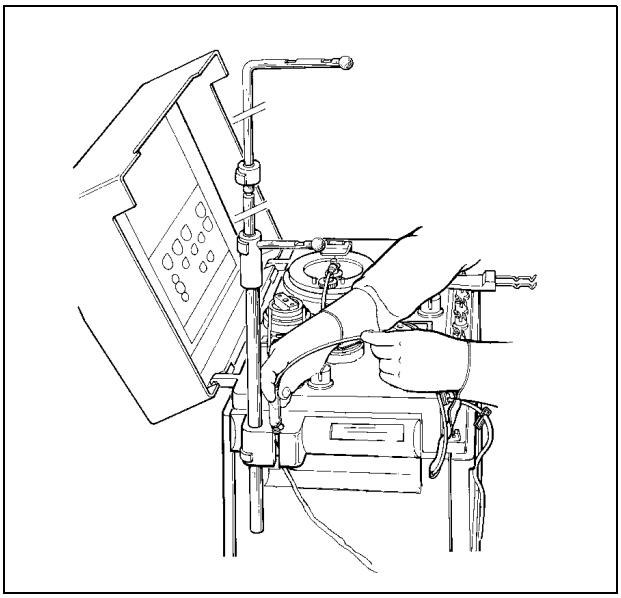


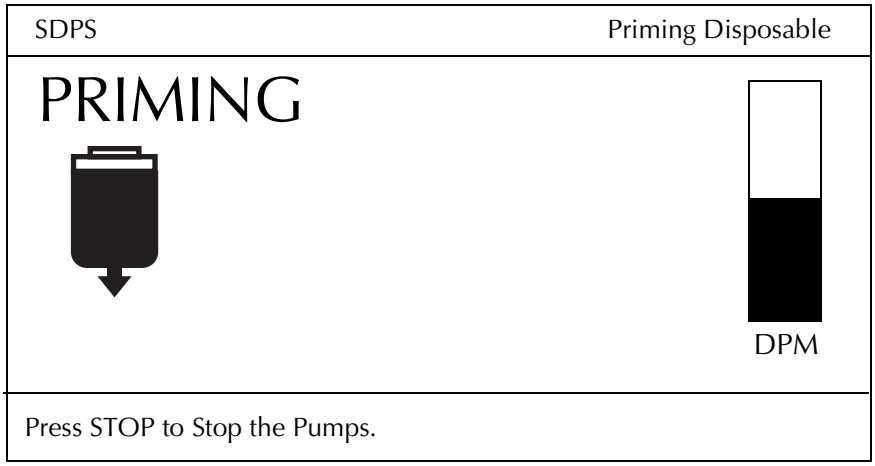
Figure 9, Drip Chamber Installation

When performing a platelet collection procedure with saline replacement, spike the saline onto the replacement line using aseptic technique. Hang the saline bag on the upper arm of the IV pole.

Warning! To ensure that the saline line is spiked onto the saline bag, follow the line visually to the dual pump manifold.

4. Press PRIME.

The following screen, indicating the current mode of operation, is shown once the PRIME key has been pressed.



The Prime mode automatically moves air from the platelet bags to the plasma bag by rotating the white pump clockwise until a decreased pressure is detected at the SPM. This reduces the amount of air that needs to be expressed from the platelet product at the end of the procedure.

Note: You should be able to see the drops of anticoagulant as the AC Pump turns. If the drip chamber is overfilled, remove the AC bag from the IV Pole, invert the bag, and squeeze the drip chamber. This brings some of the AC back into the AC bag.

Once the air has been removed from the platelet bags, the Prime mode automatically primes the disposable with anticoagulant. The Anticoagulant and Blood Pumps turn simultaneously to prime the anticoagulant line, and then the donor line, until the anticoagulant reaches DLAD 1 or 2.

Note: To ensure the saline has been spiked onto the replacement line, read the label on the saline bag and follow tubing to the manifold.

Note: Once the solutions have been attached to the disposable, a procedure should be initiated within four (4) hours.

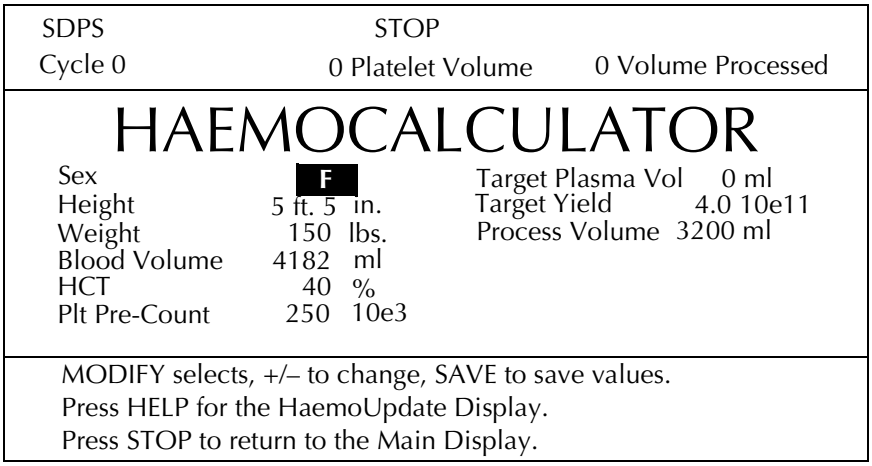
Enter Donor Statistics and Procedure Information

After AC priming, the MCS+ displays the HaemoCalculator screen. The MCS+ is now ready to be programmed for the Single Donor Platelets procedure. The HaemoCalculator screen is displayed. The preset parameters may be modified using the "+" and "–" keys. The MODIFY key is used to scroll through the listed parameters.

Haemo-Calculator

The HaemoCalculator automatically calculates the optimal process volume according to the individual donor's characteristics and the desired platelet yield.

The HaemoCalculator may be accessed at any time by pressing the HELP/HAEMOCALCULATOR key. This screen contains donor information in the left column and procedure information in the right column. The top section of the screen contains a running update of the most vital procedure statistics.



The HaemoCalculator is a program within the MCS+ that calculates the target volume of anticoagulated blood to process (process volume) to collect the desired platelet product. Table 1 gives the ranges and modifiable increments for each of the HaemoCalculator parameters. Depending on which platelet protocol has been selected (SDP, SDPS, PLP, PLPS), the factory preset values vary as indicated in the table.

Table 1, HaemoCalculator Parameters

Parameter	*Default*	*Range*	*Increment*
Sex	F	M/F	
Height	5 ft. 5 in.	4 ft. 0 in. – 7 ft. 11 in.	1 in.
Weight	150 lb.	100 lb. – 400 lb.	1 lb.
Blood Volume	4182 ml	Calculated Value	1 ml
Hematocrit	40%	30% – 60%	1%
Platelet Precount	250 10e3/µl	150 10e3 – 600 10e3/µl	1 10e3/µl
Plasma Volume SDP, SDPS PLP, PLPS	 0 ml 400 ml	 0 ml – 0 ml 0 ml – 600 ml	 – 1 ml
Target Yield	4.0 10e11	0.3 10e11 – 10.0 10e11	0.1 10e11
Process Volume	3200 ml	500 ml – 9900 ml	50 ml

Donor Information Parameters

The donor parameters entered are sex, height, weight, hematocrit, and platelet precount. These parameters are used to estimate the total blood volume. Blood volume and hematocrit are used to customize the procedure to the donor.

1. Sex. Enter the donor's sex, female (F) or male (M).
2. Height. Enter the donor's height in feet and inches.

3. Weight. Enter the donor's weight in pounds.
4. Blood Volume. Based on the sex, height, and weight of the donor, the MCS+ calculates an estimate of the total blood volume of the donor.
5. HCT. Hematocrit. Enter the hematocrit as a percentage. The donor's hematocrit is used to maintain optimal separation conditions in the bowl during the draw mode. (If only hemoglobin value is available, multiply by three to determine hematocrit value to input.)

Note: To determine donor eligibility, either a hematocrit or a hemoglobin can be used. Haemonetics recommends using a measurement instrument for which the FDA has granted pre-market clearance for the use of measuring hematocrit or hemoglobin for blood donor screening purposes.The institution should document methods for determining donor eligibility in its operating procedures. Procedures for determining the donor's eligibility relative to hematocrit or hemoglobin should be validated in accordance with the institution's procedures.

6. Platelet Precount. Enter the platelet precount to determine the total volume of anticoagulated whole blood to be processed in order to collect the programmed target yield. If a platelet precount is not available, you may choose to use an historical donor count or an average of historic counts or the program default.

Product Parameters

1. Plasma Volume is the volume of concurrent plasma to be collected during the procedure. The target plasma volume should be kept at "0" when collecting double platelet products.

Note: The Food and Drug Administration limits the total volume of plasma removed from an apheresis donor (the volume of the platelet product and the volume of concurrent plasma) to 500 ml for donors under 175 lb. and 600 ml for donors 175 lb. or more, except as specifically approved by CBER. The MCS+ will monitor the total volume of product collected excluding anticoagulant. A message will be displayed when the total product volume exceeds this limit. The operator is allowed the option to continue to follow the nomogram or to override and exceed the nomogram.
When following the nomogram, the MCS+ will reduce the volume of concurrent plasma product in favor of the collected platelet products. If the estimated volume of the platelet product is expected to exceed the nomogram, the MCS+ will lower the target yield and end the procedure.

2. Target Yield is the total number of platelets to be collected during the procedure. The target yield should be set to a value that has been validated to meet the institution's requirements for acceptable platelet products.

3. Process Volume is the total volume of anticoagulated blood to be processed during the procedure. The process volume is calculated by the MCS+ based on the target yield and the donor blood volume and platelet precount.

Note: You can access the HaemoCalculator by pressing the HELP/HAEMOCALCULATOR key twice. Any of the parameters in the HaemoCalculator may be modified during the procedure. For example, if the donor's actual platelet precount is not immediately available, you may modify this value from the preset parameter when it is available. To return to the Main Screen, either press the HELP/HAEMOCALCULATOR key or press the illuminated current mode key.

Double Product Collection Guidelines

The following guidelines are provided to help target a platelet collection that produces two transfusable platelet products from a single donor (Double Product):

1. The target yield should be set to a value that has been validated to meet the institution's requirements for acceptable platelet products.

Note: It is at the user's discretion to establish donor guidelines for collecting double platelet products through process validation.

HaemoUpdate

The HaemoUpdate screen contains a full detailed continuous update of all procedure statistics. Press the HELP key once to access the HaemoUpdate screen. The left hand column of the HaemoUpdate screen gives an update of the procedure information; the right hand column gives detailed product volume statistics.

SDPS	STOP	Ready to Go
Cycle 0	0 Platelet Volume	0 Volume Processed

HAEMOUPDATE

AC Volume Used	0 ml	Plasma Volume	0 ml
Elapsed Time	0 ml	Platelet Volume	0 ml
Target Cycles	7	Estimated Yield	0.0 10e11
NaCl Volume Used	0 ml	Target Yield	4.0 10e11

Press HELP for HaemoCalculator.
Press STOP to return to Main Display.

Procedure Update Information

1. AC Volume Used. This is the total volume of anticoagulant used in ml.
2. Elapsed Time is the number of minutes since the procedure was started.
3. Target Cycles is the total number of cycles the MCS+ expects to perform to process the volume of anticoagulated whole blood needed to collect the target yield of platelets.
4. NaCl Volume Used is the total volume of saline used during the procedure.

Product Information

1. Plasma Volume is the total volume of plasma collected into the plasma bag. The volume of plasma collected is based on the weigher reading. The weigher conversion factor used is 1.026 g/ml.
2. Platelet Volume is the current volume of the platelet product. The Platelet Volume is calculated from the volume of plasma removed from the plasma bag during the surge platelet collection. The weigher conversion factor used is 1.026 g/ml.
3. Estimated Yield is estimated number of platelets collected.
4. Target Yield is the number of platelets to be collected as programmed in the HaemoCalculator.

Modify Parameters

The Modify Parameters screen can be accessed from the Main Screen at any time by pressing the MODIFY key. This screen contains a number of less frequently used programmable parameters. The top section of the screen contains a continuous update of the most vital procedure statistics.

SDPS	STOP	Ready To Go
Cycle 0	0 Platelet Volume	0 Volume Processed

MODIFY PARAMETERS

Cuff Pressure	50 mmHg	NaCl Vol/Cycle	40 ml
Return Speed	120 ml/min		
AC Ratio	1: 9		
Min. Plt. Volume	200 ml		
AC Bag Volume	500 ml		

MODIFY selects, +/– to change, SAVE to save values.

Press STOP to return to the Main Display.

Table 2 gives the ranges and increments for each of the programmable Modify Parameters. Depending on which platelet protocol has been selected, the factory preset default values may vary.

Table 2: Modifiable Parameters

Parameter	Default	Range	Increment
Cuff Pressure	50 mmHg	0 mmHg – 100 mmHg	5 mmHg
Return Speed	120 ml/min.	20 ml/min. – 150 ml/min.	5 ml/min.
AC Ratio	1:9	1:8 – 1:16	1:1
Min. Plt. Volume	200 ml	0 ml – 600 ml	5 ml
AC Bag Volume	500 ml	0 ml – 1000 ml	50 ml
NaCl Volume/Cycle SDPS, PLPS	40 ml	0 ml – 100 ml	5 ml

1. Cuff Pressure. This determines the cuff pressure. The cuff is inflated and deflated automatically by the MCS+ during the procedure.
2. Return Speed. This is the pump rate that the MCS+ maintains during the Return mode of the procedure. When the flow of blood to the donor is less than the set return speed, the pressure in the donor line increases. This change in pressure at the DPM results in a filling of the DPM bar graph on the main display. When the pressure bar completely fills, the MCS+ decreases its return speed. This allows the pressure to decrease and the bar graph lowers.
3. AC Ratio. This is the ratio of anticoagulant to anticoagulated whole blood.
4. Min. Plt. Volume. This parameter controls the minimum volume of the platelet product. If the total platelet product volume is less than the programmed value, the MCS+ automatically adds plasma volume to the product in order to obtain the minimum product volume.
   - If a double platelet product has been selected, the MCS+ automatically sets the minimum platelet volume to 400 ml.
5. AC Bag Volume. This is the volume of the anticoagulant bag used for the procedure. The MCS+ displays a notice message at the beginning of the Return cycle to alert the operator if the volume of anticoagulant used is expected to exceed this value during the next Draw cycle.
6. NaCl Volume/Cycle. This is the volume of saline fluid returned with the red cells and plasma to the donor to compensate for the product collected.

Protocol

SINGLE DONOR PLATELETS (SDP, SDPS)

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PREPARE THE MCS+

Power up the MCS+

Verify that the appropriate SDP/PLP Protocol Card is installed into the Protocol Card slot on the right side of the MCS+.

Power on the MCS+ and prompt it through its self-test as explained in the section, "Platelet Collections: General."

Select the SDP or SDPS Protocol.

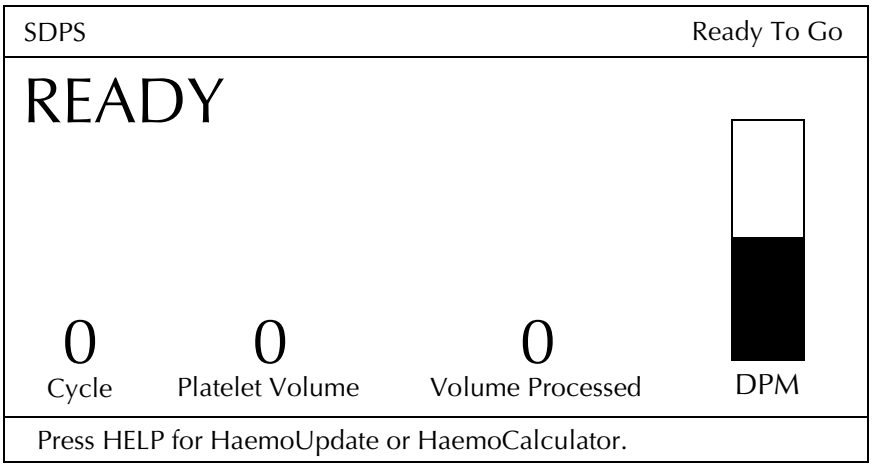
Install and prime the disposable

Install and prime the disposable as explained in the section, "Platelet Collections: General."

Enter Statistics and Procedure Information

Enter the donor statistics and procedure information. For detailed information refer to the section, "Platelet Collections: General."

When the statistics and procedure information have been entered correctly, press STOP. Pressing STOP advances the system to the Ready display as shown (the actual values will vary).



The top right-hand section of the Display Screen, referred to as "status update," indicates what is happening in the bowl based on what the optics are reporting. In the middle of the screen, the mode of the cycle is shown in large text. For your

convenience, the cycle number, platelet volume, and volume processed are continuously displayed on the lower middle portion of the screen. The lower portion of the screen gives directions for obtaining more information.

The continuous "status update" is shown for the duration of the procedure. The left of the screen displays an icon with an arrow that indicates the direction of flow. The right of the screen displays a bar graph that represents pressure in the donor line.

PREPARE THE DONOR

Donor Preparation

Prepare the donor and perform the venipuncture following the institution's standard operating procedures.

Preprocedure Blood Sample Collection

Warning! Haemonetics recommends the use of a preprocedure sample to avoid potential saline dilution of blood samples used for viral marker testing.

Warning! Haemonetics recommends handling all biologically contaminated materials pursuant to those policies and procedures dictated by the institution's Exposure Control Plan.

Obtain a preprocedure blood sample from the donor following standard operating procedures for sampling blood.

1. Before performing a venipuncture, clamp the anticoagulant and blood line twin tubing near the needle connector with a hemostat.

Warning! Failure to clamp the anticoagulant and blood line twin tubing may result in dilution of the sample with anticoagulant. A diluted blood sample may cause inaccurate test results.

2. Open the clamp on the sample pouch tubing and allow the necessary blood volume to flow into the sample pouch. Close the clamp on the sample pouch.
3. Place a hermetic seal on the sample pouch tubing between the needle connector and the sample pouch.
4. Remove the sample pouch from the disposable set (optional).
5. Remove the hemostat from the anticoagulant and blood line twin tubing.

Note: The Draw cycle may be initiated at this point by pressing the DRAW key.

6. Using standard venipuncture supplies and aseptic technique, collect the necessary samples from the sample pouch.

PERFORM THE PROCEDURE

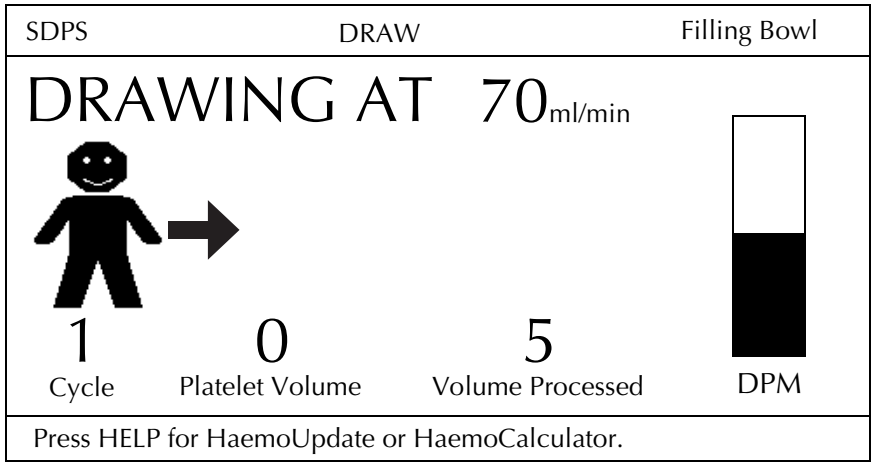
At this time the collection procedure can be started by pressing DRAW.

Once the DRAW key is pressed, the Cuff is inflated, the Pumps and Centrifuge are turning, and all monitoring components used in Draw are activated. Also, during the first Draw mode, the Weigher is automatically tared (reset) to 0 to subtract the weight of the plasma bag.

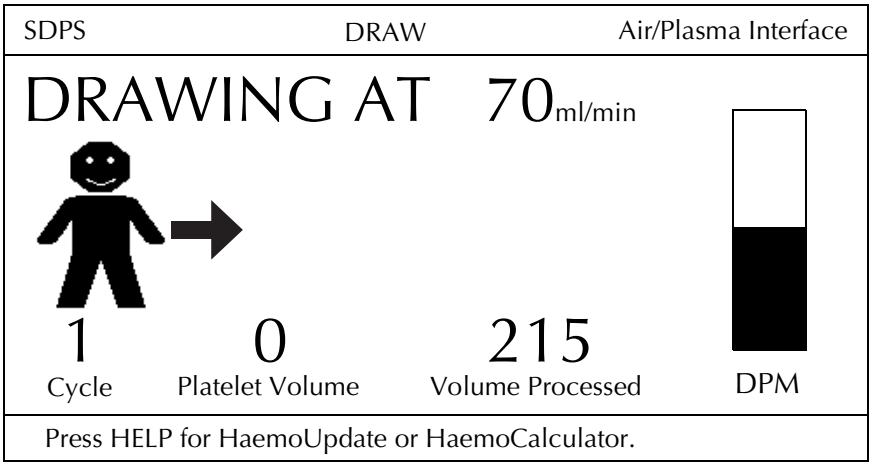
Note: If the RETURN key is pressed at any time during the Draw cycle, the pumps will stop but the centrifuge will continue to spin. The operator will be given the option to continue the Draw cycle or begin the Return cycle. The operator may also elect to end the procedure after the Return cycle is completed.

Draw Mode

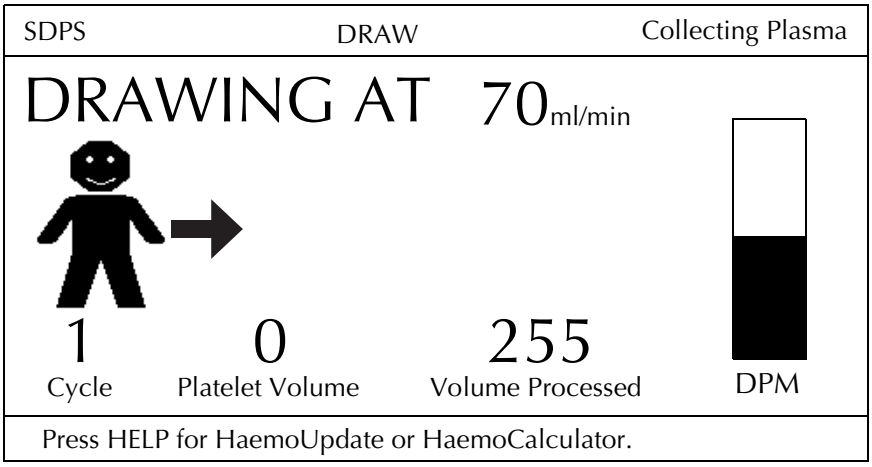
1. The MCS+ fills the disposable centrifuge bowl with anticoagulated whole blood. The White Valve is open as the sterile air displaced from the bowl is diverted to the air bag. During this time the following display appears.



2. When the air/plasma interface is detected by the Bowl Optics, the following screen appears.

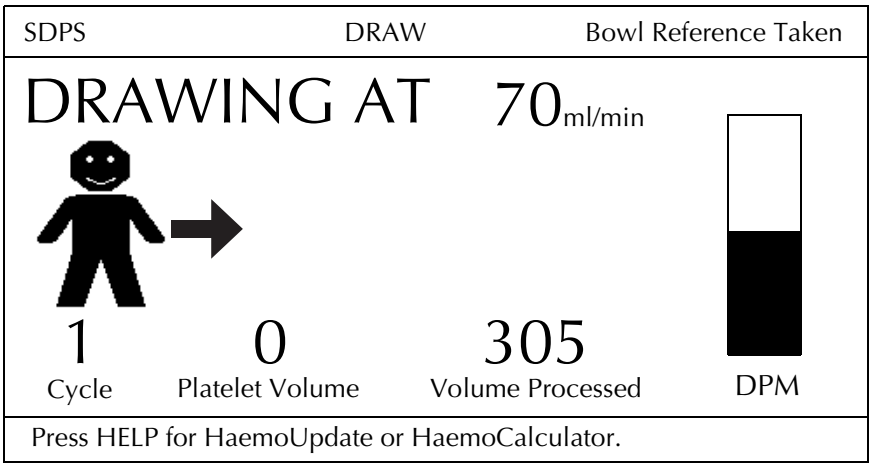


3. After all the sterile air has been displaced from the bowl, the plasma begins to exit the bowl through the effluent port. Approximately 10 ml of plasma is placed into the air bag. The White Valve closes and the Yellow Valve opens. The plasma is sent directly to the plasma bag as indicated by the following display.

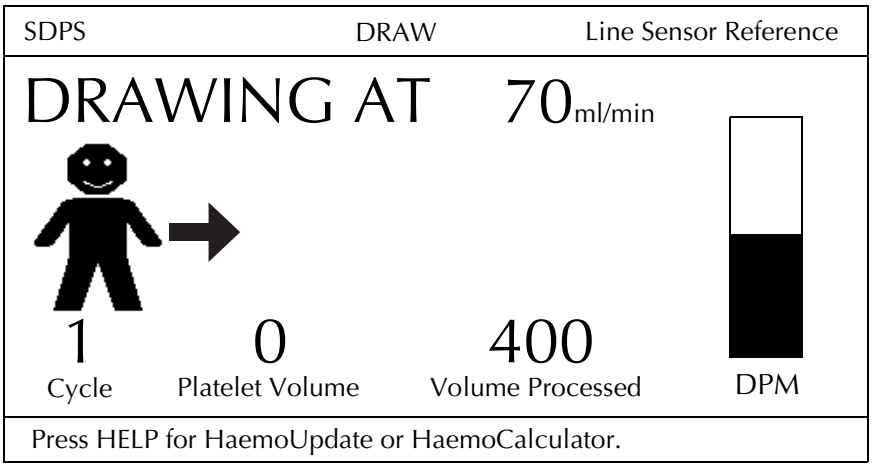


4. During the first cycle (approximately one minute after the Collecting Plasma status update message appears), the MCS+ activates the White Pump, which begins recirculation of plasma through the bowl.

5. After approximately another minute, a Bowl Optics reference is taken. The Bowl Optics reference is a reference voltage proportional to the optical density of the donor's plasma, measured by the Bowl Optics. This helps to determine when Surge should begin. The following screen is displayed.

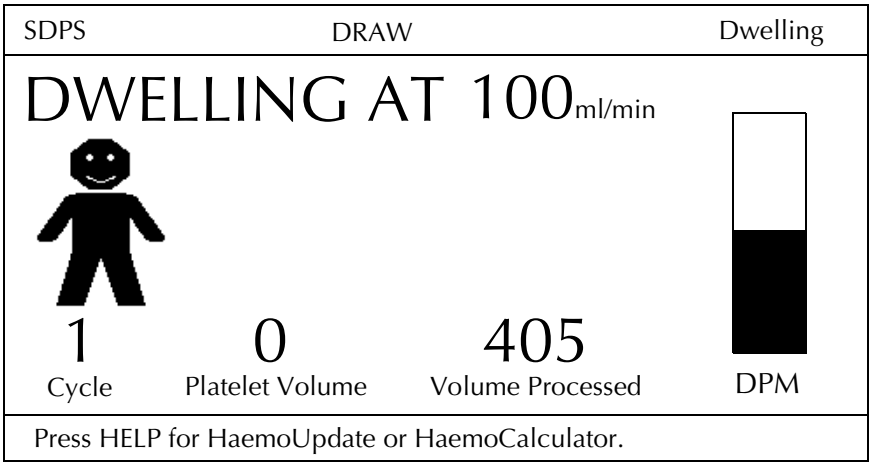


6. The next event is the detection of the plasma/buffy coat interface by the Bowl Optics, at which point the Line Sensor reference is taken and the following screen is displayed.

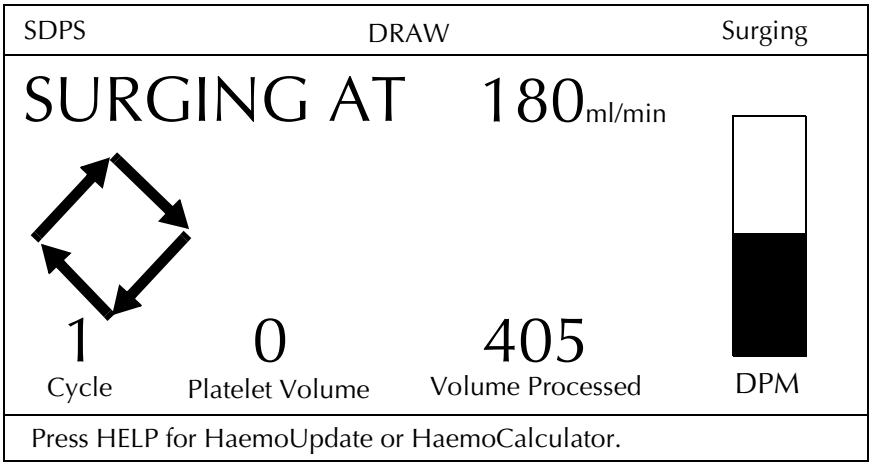


Dwell and Surge

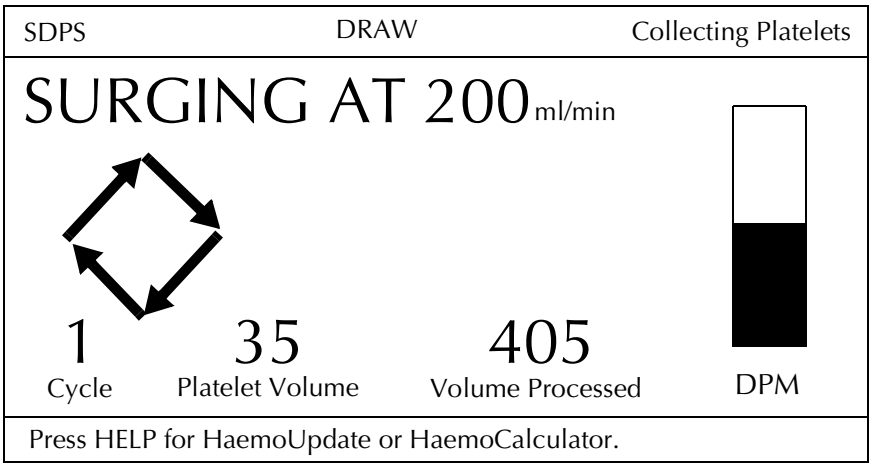
1. The detection of the plasma/buffy coat interface initiates Dwell, during which plasma is recirculated at 100 ml/min. through the bowl in order to enhance the separation of cell layers. All air detectors are tested at the beginning of each Dwell phase. The following screen is displayed.



2. After Dwell, Surge begins. During Surge, plasma is rapidly pumped from the plasma bag into the Latham bowl, as indicated in the following display.



3. The recirculation of plasma continues until the effluent Line Sensor detects the presence of platelets. When this occurs, the Green Valve to the platelet bags opens and platelets are collected. The following screen is displayed.



4. This continues until the End Collection Point is reached. At this time, the blood pump gradually reduces speed, the centrifuge stops, and the platelet collection ends.

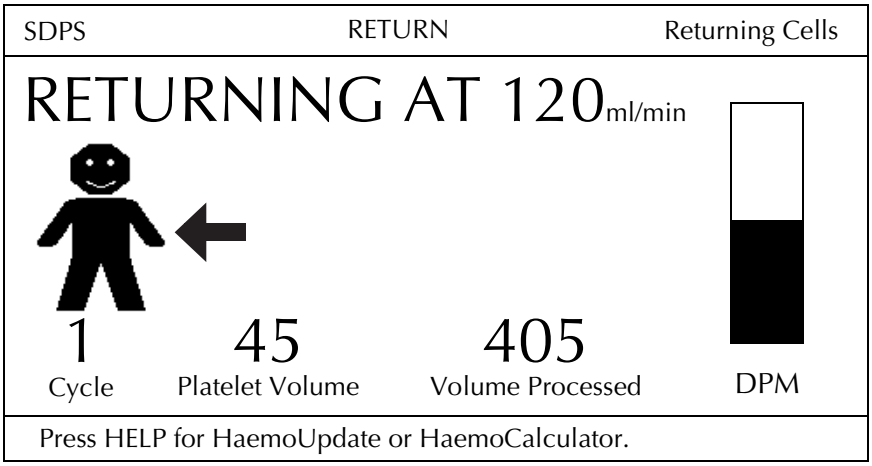
Return Mode

Once the Centrifuge has come to a complete stop, Return begins.

Note: At the start of the first Return cycle, the replacement line is primed by pumping 15 ml of saline into the bowl (SDPS only).

1. Plasma from the plasma bag and red cells from the bowl are returned simultaneously. During Return, the following screen is displayed. When performing an SDPS procedure, saline will be mixed with plasma and red blood cells.

Note: The MCS+ will retain some plasma every cycle to allow for recirculation of plasma in the next cycle.

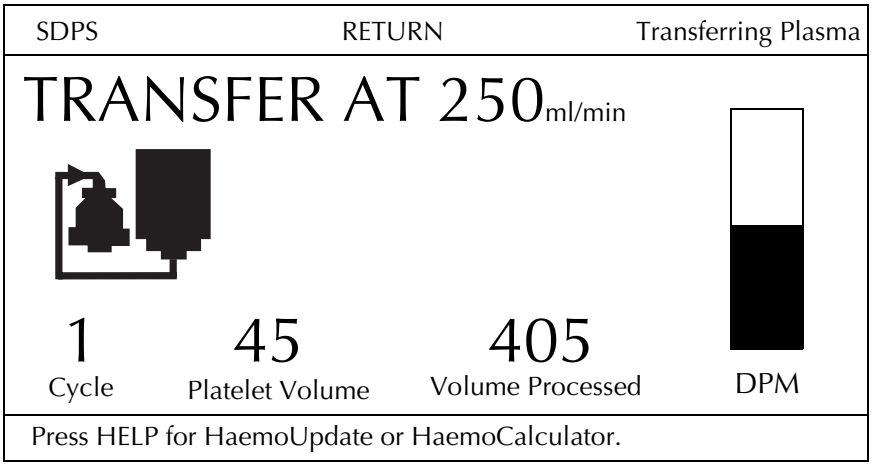


Note: Air from the air bag is displaced into the bowl as the bowl is being emptied.

2. Once the BLAD detects air, the Blood Pump stops and the White Pump transfers plasma into the bowl.

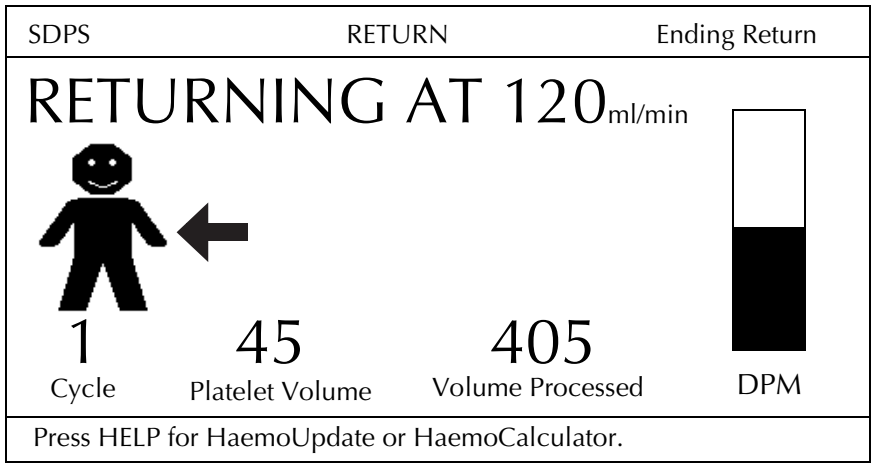
Note: The bowl spins as plasma is transferred into the bowl to facilitate mixing.

The following screen is displayed.

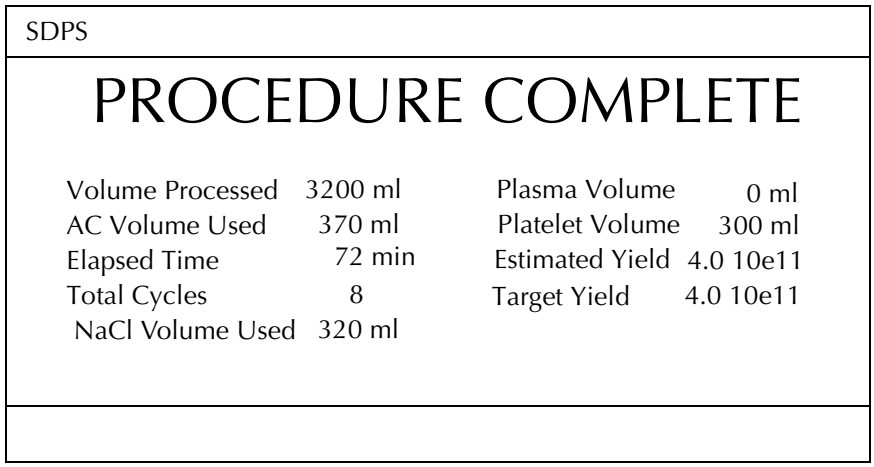


3. The White Pump will stop and the remaining RBCs in the bowl will be returned to the donor through the Blood Pump.

4. When the BLAD detects air again, blood will continue to be returned until the filter chamber is empty. The following message is displayed.



These steps in the flow process are repeated until the programmed parameters are achieved. Upon completion of the final Return, the following screen is displayed.



This message remains on the screen until the disposable set is removed from the MCS+. Another procedure may begin as soon as a new disposable is installed.

Note: The residual amount of blood in the collection set at the conclusion of a normal procedure is approximately 55 ml, of which approximately 45 ml is plasma.

Clean any spills immediately.

Post-procedure Sample Collection (Optional)

Warning! Haemonetics recommends the use of a preprocedure sample to obtain blood samples for viral marker testing. Haemonetics recommends a post-procedure sample be used for obtaining cell counts only.

At the end of the procedure an optional post-procedure sample may be obtained following the procedure outlined below in combination with standard operating procedures for sampling blood.

Warning! If the disposable includes an injection port, do not use this port before hermetically sealing the collected product(s). Use of this port compromises the sterile fluid pathway.

1. Place a hermetic seal on the blood line tubing near the needle connector.
2. Seal or clamp the anticoagulant line tubing near the needle connector.

Warning! Failure to seal or clamp the anticoagulant and blood line tubing may result in dilution of the sample with anticoagulant. A diluted blood sample may cause inaccurate test results.

3. Using standard venipuncture materials, collect an adequate sample of blood for post-procedure testing from the injection port at the needle site. Haemonetics recommends discarding the first 3 to 5 ml from the tubing. The sample collected after discard is representative of the donor whole blood.

COMPLETING THE PROCEDURE

1. Follow the procedure outlined in the section entitled “Post-procedure Sample Collection (Optional)” for obtaining an optional post-procedure sample.
2. Place a hermetic seal between the needle and the product.

Warning! Do not remove the needle before hermetically sealing the collected product(s). Removing the needle compromises the sterile fluid pathway.

3. Remove the venipuncture needle.
4. Apply a pressure dressing and release the donor according to standard operating procedures.
5. Remove any residual air from the platelet bag.

To remove air from platelet bag:

a. Gently roll the platelet bag containing the platelet concentrate from the bottom.

b. Open the White Valve and Green Valve manually.

c. Transfer air from the platelet bag to the air bag.

d. When all the air is expressed, allow the valves to close.

6. Obtain product sample.

For Single Platelet Products

To obtain a platelet product sample:

1. Hermetically seal the green-striped line at the T-connector and remove platelet bags from the disposable set.
2. Open the sample pouch and allow the fluid in the tubing between the sample pouch and the platelet bag to drain into the platelet bag. Open the slide clamp on the second platelet bag to help drain the tubing.
3. Close the slide clamps to both platelet bags. Manually mix the platelet product thoroughly with a rocking back-and-forth motion for at least 30 seconds.
4. Open the slide clamp to the platelet bag, invert the bag so the ports are down, and allow the platelets to flow into the sample pouch. Fill the sample pouch completely.
5. Raise the sample pouch to allow the product in the sample pouch to drain back into the platelet bag.

Note: Filling the pouch completely, before taking only the necessary volume for sampling, washes any residual cells from the plastic surface and is an important step in ensuring sample accuracy.

6. Transfer a platelet sample from the platelet bag into the sample pouch. Stop when a volume sufficient for sampling has been achieved. Invert the platelet bag to squeeze air into the sample pouch. Close the clamp on the sample pouch. Reclamp the line adjacent to the platelet bag.
7. Hermetically seal the sample pouch tubing and remove for a platelet count.

Warning! Any potential opening within the disposable set prior to the platelet concentrate being removed requires that the product storage life be reduced to 24 hours.

8. Cut the sample pouch tubing and transfer sample into an EDTA tube.
9. Obtain the cell counts from the sample.

10. Obtain the platelet product volume:
    a. Place the platelet bags containing the filtered platelet product on a calibrated gram scale. Record the total weight.
    b. Subtract the tare weight from the total weight. This is the product weight.
    c. Divide the product weight by 1.026 g/ml. This is the product volume.
11. Calculate the total platelet product yield.
12. If the product yield exceeds the capacity of one platelet bag, hang the platelet bags port down with both clamps open to allow the platelet concentrate to flow between both platelet bags until an (approximately) equal amount of concentrate is in each bag.
13. The platelets are ready to be stored.
14. Remove disposable and dispose of in accordance with standard operating procedures.

For Double Platelet Products

To obtain a platelet product sample:

1. Open the sample pouch and allow the fluid in the tubing between the sample pouch and the platelet bag to drain into the platelet bag. Open the slide clamp on the second platelet bag to help drain the tubing.
2. Close the slide clamps to both platelet bags. Manually mix the platelet product thoroughly with a rocking back-and forth motion for at least 30 seconds.
3. Clamp the sample pouch and open the slide clamp to the bag containing the platelet product. Allow flow of platelet concentrate into the line between the platelet and plasma bags for a pre-split product sample.
4. Hermetically seal and remove the tubing and perform a platelet count.

Warning! If the platelet yield exceeds the storage capacity of two platelet bags combined, additional platelet storage bags should be attached using a sterile connection device.

5. Cut the sample pouch tubing and transfer sample into an EDTA tube.
6. Obtain the cell counts from the sample.
7. Obtain the platelet product volume:
    a. Place the platelet bags containing the filtered platelet product on a calibrated gram scale. Record the total weight.
    b. Subtract the tare weight from the total weight. This is the product weight.
    c. Divide the product weight by 1.026 g/ml. This is the product volume.
8. Calculate the total platelet product yield.

9. Open the clamps to both extended storage bags. Divide the product evenly by allowing the platelet concentrate to flow between the two bags. A validated gram scale should be used to ensure an equal split of the platelet concentrate.
10. Steps 10a through 10g describe an optional procedure to validate that the concentration in both units is equivalent.
    To obtain a sample from each individual unit:
    a. Using a tubing stripper, empty platelet product remaining in the 14″ tubing into the first platelet unit.
    b. Manually mix the platelet product thoroughly with a rocking back-and-forth motion for at least 30 seconds.
    c. Using a tubing stripper collect a platelet sample from the platelet unit into the 14″ tubing.
    d. Hermetically seal off a 5″ section of the 14″ tubing.
    e. Cut the 5″ tubing segment and transfer the sample into an EDTA tube.
    f. Obtain a cell count for the platelet unit.
    g. Repeat steps for second platelet unit.
11. Separate the platelet bags. Strip platelet concentrate into the tubing remaining with each extended storage bag.
12. The platelets are ready to be stored.
13. Remove disposable and dispose of in accordance with standard operating procedures.

Protocol

PLATELETS AND PLASMA (PLP, PLPS)

PREPARE THE MCS+ 2
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PREPARE THE MCS+

Power up the MCS+

Verify that the appropriate SDP/PLP Protocol Card is installed into the Protocol Card slot on the right side of the MCS+.

Power on the MCS+ and prompt it through its self-test as explained in the section, "Platelet Collections: General."

Select the PLP or PLPS Protocol.

Install and prime the disposable

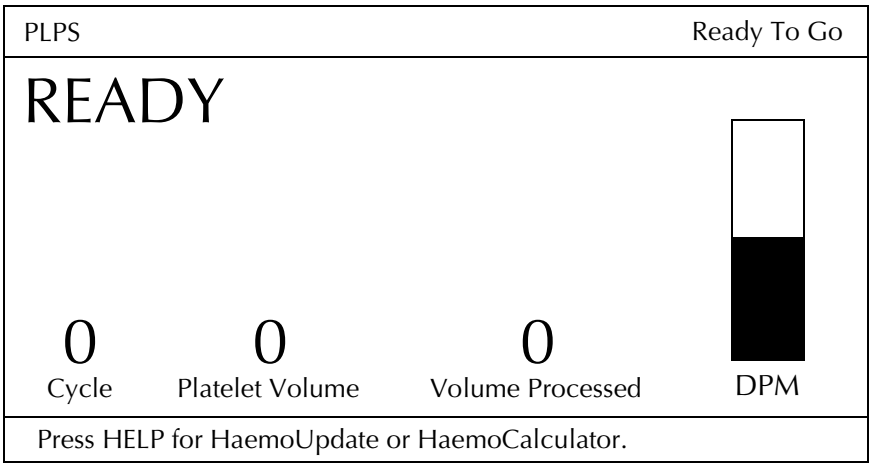
Install and prime the disposable as explained in the section, "Platelet Collections: General."

Enter Statistics and Procedure Information

Enter the donor statistics and procedure information. For detailed information refer to the section, "Platelet Collections: General."

Note: Double platelet products should not be collected when using the Platelets and Plasma Protocols.

When the statistics and procedure information have been entered correctly, press STOP. Pressing STOP advances the system to the Ready display as shown (the actual values will vary).



The top right-hand section of the Display Screen, referred to as "status update," indicates what is happening in the bowl based on what the optics are reporting. In the middle of the screen, the mode of the cycle is shown in large text. For your convenience, the cycle number, platelet volume, and volume processed are continuously displayed on the lower middle portion of the screen. The lower portion of the screen gives directions for obtaining more information.

The continuous "status update" is shown for the duration of the procedure. The left of the screen displays an icon with an arrow that indicates the direction of flow. The right of the screen displays a bar graph that represents pressure in the donor line.

Prepare the Donor

Donor Preparation

Prepare the donor and perform the venipuncture following standard operating procedures.

Preprocedure Blood Sample Collection

Warning! Haemonetics recommends the use of a preprocedure sample to avoid potential saline dilution of blood samples used for viral marker testing.

Warning! Haemonetics recommends handling all biologically contaminated materials pursuant to those policies and procedures dictated by the institution's Exposure Control Plan.

Obtain a preprocedure blood sample from the donor following standard operating procedures for sampling blood.

1. Before performing a venipuncture, clamp the anticoagulant and blood line twin tubing near the needle connector with a hemostat.

Warning! Failure to clamp the anticoagulant and blood line twin tubing may result in dilution of the sample with anticoagulant. A diluted blood sample may cause inaccurate test results.

2. Open the clamp on the sample pouch tubing and allow the necessary blood volume to flow into the sample pouch. Close the clamp on the sample pouch.

3. Place a hermetic seal on the sample pouch tubing between the needle connector and the sample pouch.
4. Remove the sample pouch from the disposable set (optional).
5. Remove the hemostat from the anticoagulant and blood line twin tubing.

Note: The Draw cycle may be initiated at this point by pressing the DRAW key.

6. Using standard venipuncture supplies and aseptic technique, collect the necessary samples from the sample pouch.

PERFORM THE PROCEDURE

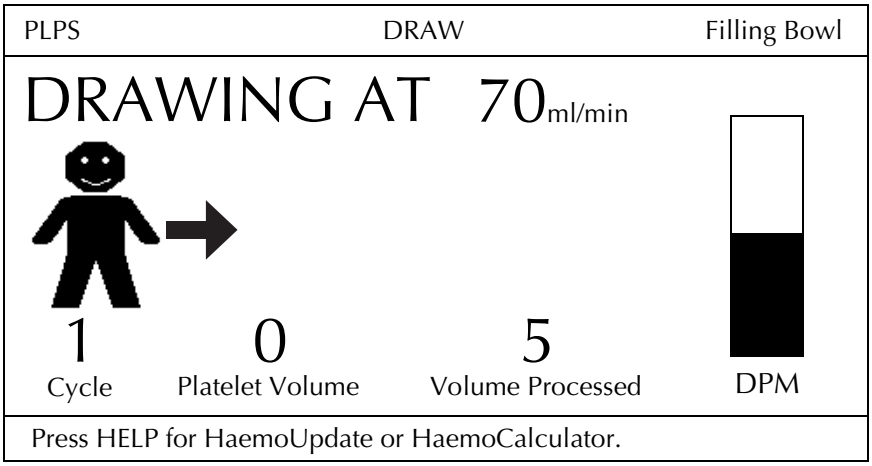
At this time, the collection procedure can be started by pressing DRAW.

Once DRAW is pressed, the Cuff is inflated, the Pumps and Centrifuge are turning, and all monitoring components used in Draw are activated. Also, during the first Draw mode, the Weigher is automatically tared (reset) to 0 to subtract the weight of the plasma bag.

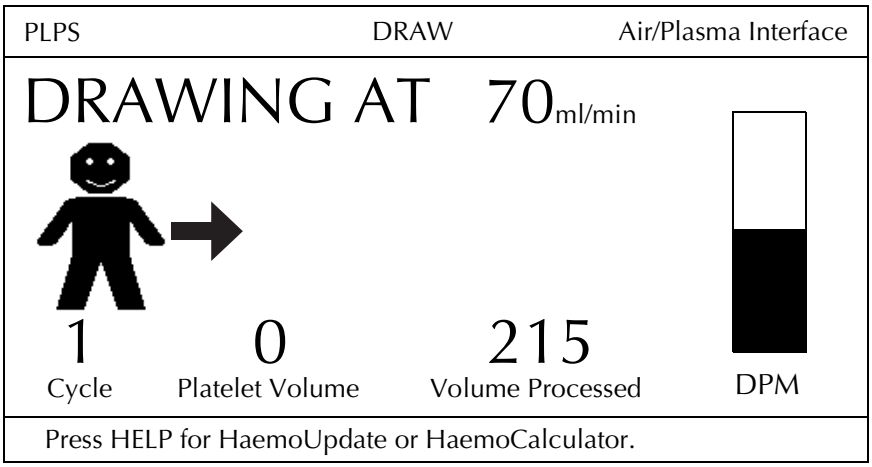
Note: If the RETURN key is pressed at any time during the Draw cycle, the pumps will stop but the centrifuge will continue to spin. The operator will be given the option to continue the Draw cycle or begin the Return cycle. The operator may also elect to end the procedure after the Return cycle is completed.

Draw Mode

1. The MCS+ fills the disposable centrifuge bowl with anticoagulated whole blood. The White Valve is open as the sterile air displaced from the bowl is diverted to the air bag. During this time the following display appears.

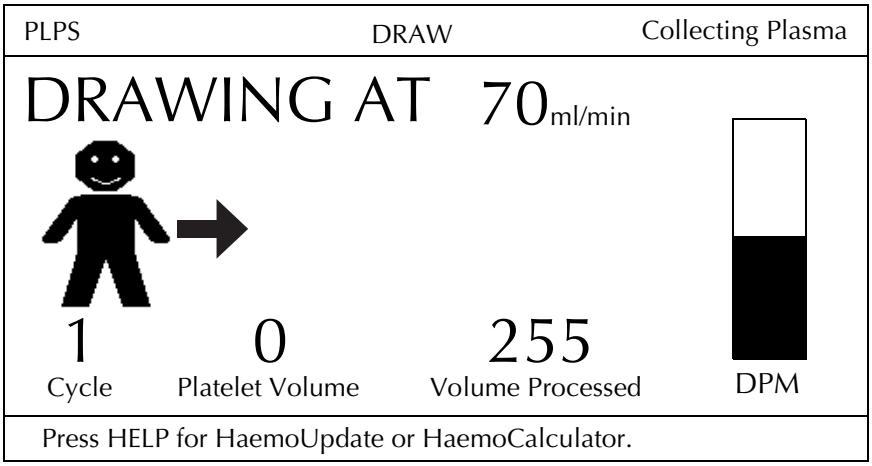


2. When the air/plasma interface is detected by the Bowl Optics, the following screen appears.

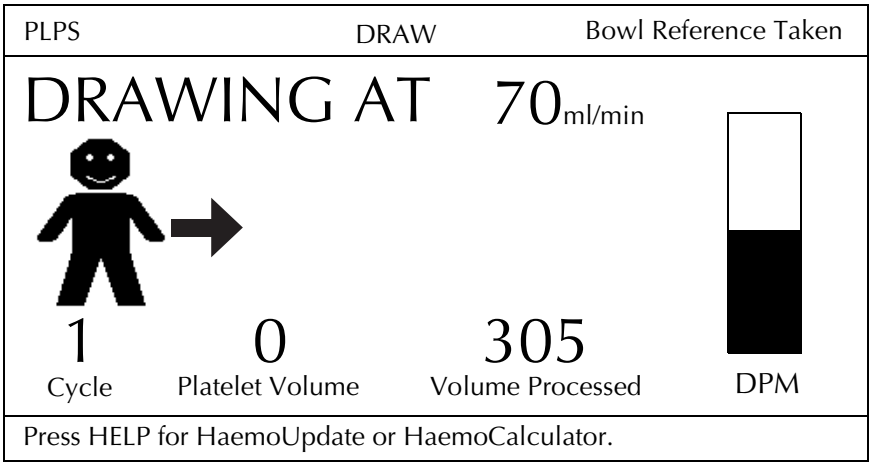


3. After all the sterile air has been displaced from the bowl, the plasma begins to exit the bowl through the effluent port. Approximately 10 ml of plasma is placed into the air bag. The White Valve closes and the Yellow Valve opens. The plasma is sent directly to the plasma bag as indicated by the following display.

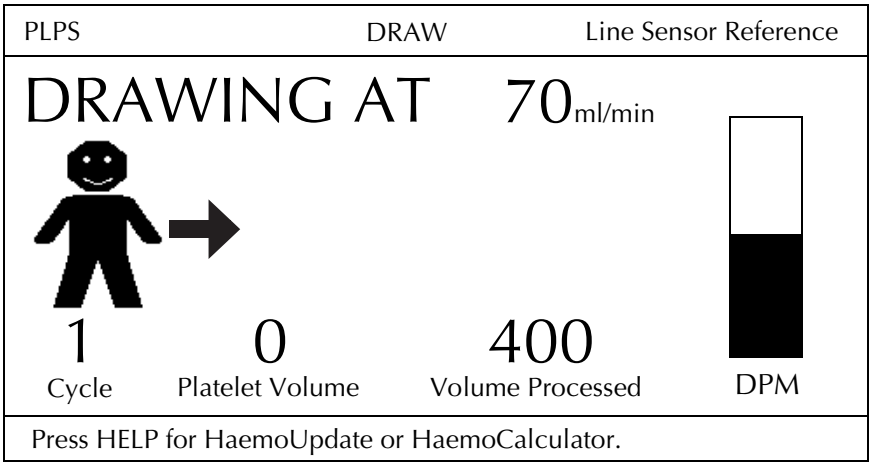
4. During the first cycle (approximately one minute after the Collecting Plasma status update message appears), the MCS+ activates the White Pump, which begins recirculation of plasma through the bowl.



5. After approximately another minute, a Bowl Optics reference is taken. The Bowl Optics reference is a reference voltage proportional to the optical density of the donor's plasma, measured by the Bowl Optics. This helps to determine when Surge should begin. The following screen is displayed.

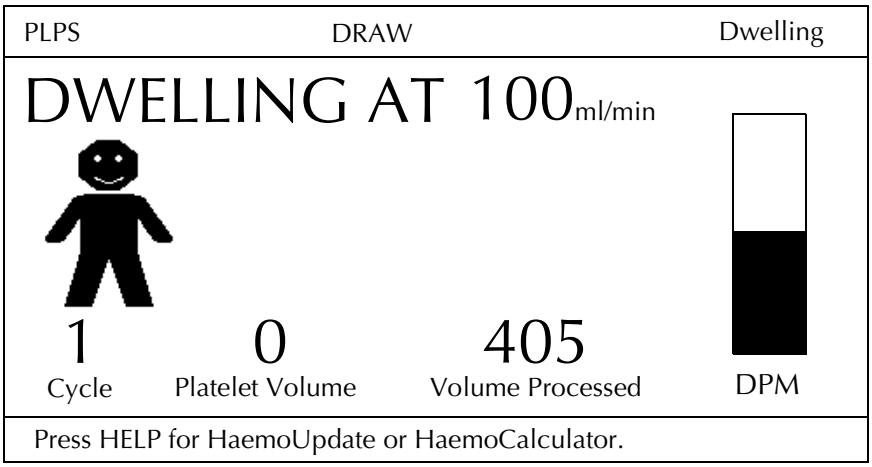


6. The next event is the detection of the plasma/buffy coat interface by the Bowl Optics, at which point the Line Sensor reference is taken and the following screen is displayed.

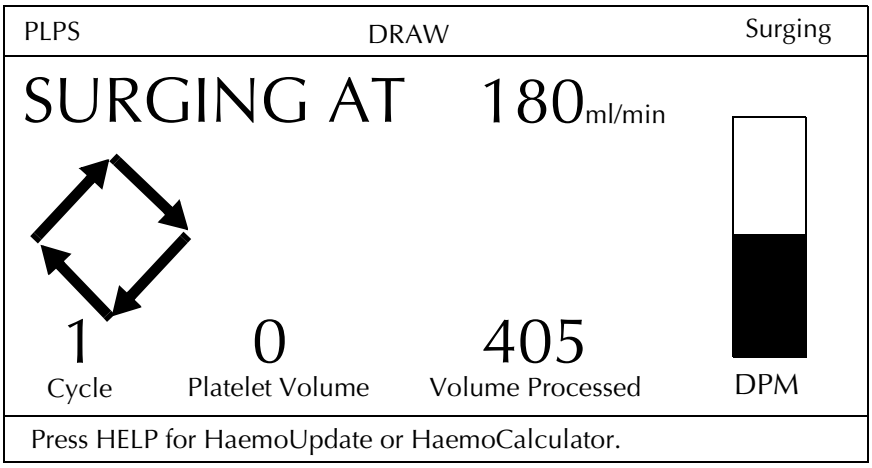


Dwell and Surge

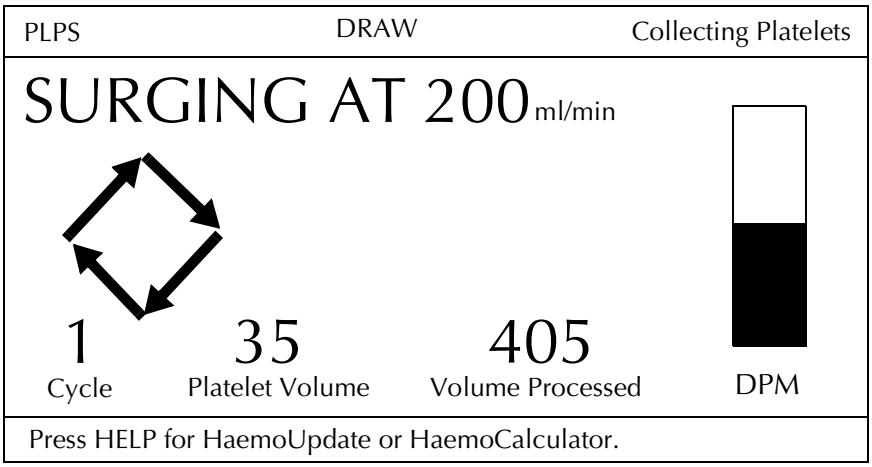
1. The detection of the plasma/buffy coat interface initiates the Dwell phase, during which plasma is recirculated at 100 ml/min. through the bowl in order to enhance the separation of cell layers. All air detectors are tested at the beginning of each Dwell phase. The following screen is displayed.



2. After Dwell, Surge begins. During Surge, plasma is rapidly pumped from the plasma bag into the Latham bowl, as indicated in the following display.



3. The recirculation of plasma continues until the effluent Line Sensor detects the presence of platelets. When this occurs, the Green Valve to the platelet bags opens and platelets are collected. The following screen is displayed.



4. This continues until the End Collection Point is reached. At this time the Blood Pump gradually reduces speed, the centrifuge stops and the platelet collection ends.

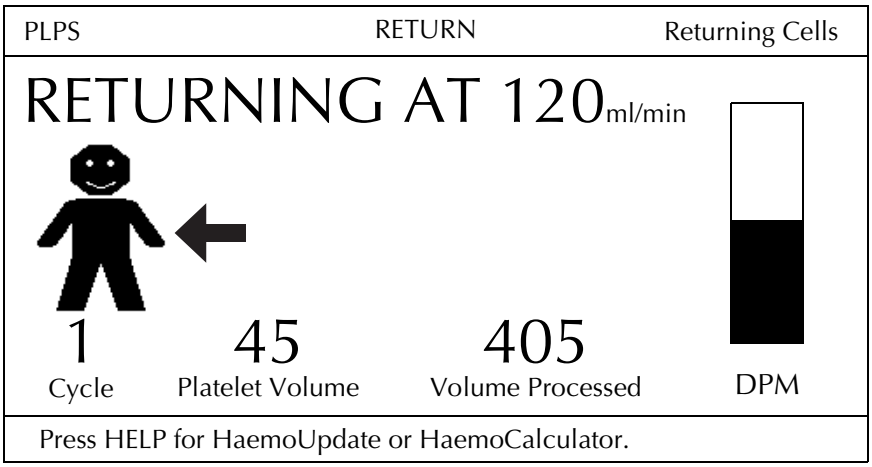
Return Mode

Once the Centrifuge has come to a complete stop, Return begins.

Note: At the start of the first Return cycle, the replacement line is primed by pumping 15 ml of saline into the bowl (PLPS only).

1. Plasma from the plasma bag and red cells from the bowl are returned simultaneously. During Return, the following screen is displayed. When performing a PLPS procedure, saline will be mixed with plasma and red blood cells.

Note: The MCS+ will retain some plasma every cycle to allow for recirculation of plasma in the next cycle.

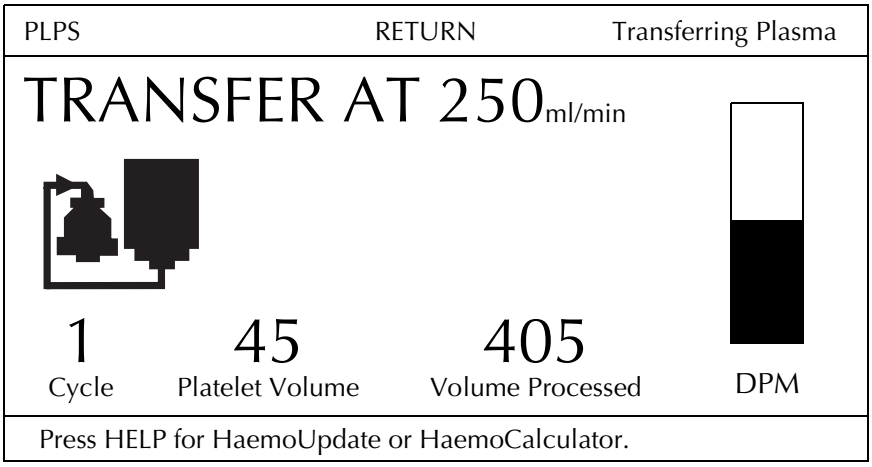


Note: Air from the air bag is displaced into the bowl as the bowl is being emptied.

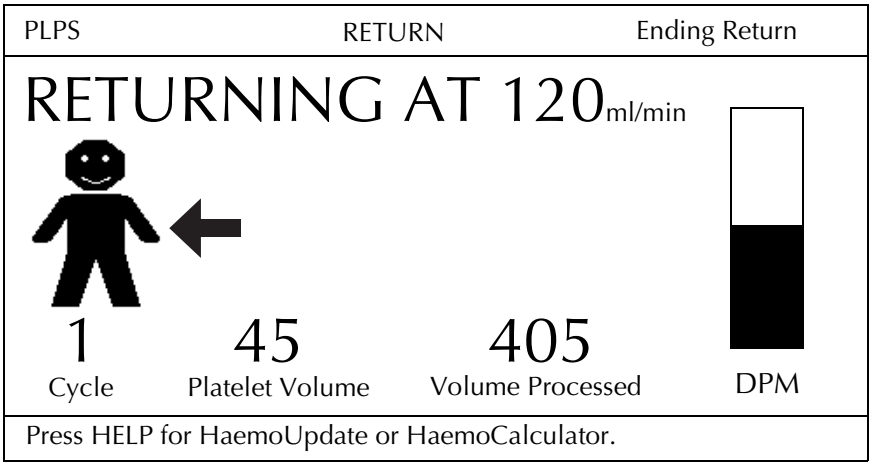
2. Once the BLAD detects air, the Blood Pump stops and the White Pump transfers plasma into the bowl.

Note: The bowl spins as plasma is transferred into the bowl to facilitate mixing.

The following screen is displayed.



3. The White Pump will stop and the remaining RBCs in the bowl will be returned to the donor through the Blood Pump.
4. When the BLAD detects air again blood will continue to be returned until the filter chamber is empty. The following message is displayed.



These steps in the flow process are repeated until the programmed parameters are achieved. Upon completion of the final Return, the following screen is displayed.

PLPS

PROCEDURE COMPLETE

Volume Processed	3200 ml	Plasma Volume	200 ml
AC Volume Used	370 ml	Platelet Volume	300 ml
Elapsed Time	72 min	Estimated Yield	4.0 10e11
Target Cycles	8	Target Yield	4.0 10e11
NaCl Volume Used	320 ml		

This message remains on the screen until the disposable set is removed from the MCS+. Another procedure may begin as soon as a new disposable is installed.

Note: The residual amount of blood in the collection set at the conclusion of a normal procedure is approximately 55 ml, of which approximately 45 ml is plasma.

Clean any spills immediately.

Post-procedure Sample Collection (Optional)

Warning! Haemonetics recommends the use of a preprocedure sample to obtain blood samples for viral marker testing. Haemonetics recommends a post-procedure sample be used for obtaining cell counts only.

At the end of the procedure an optional post-procedure sample may be obtained following the procedure outlined below in combination with standard operating procedures for sampling blood.

Warning! If the disposable includes an injection port, do not use this port before hermetically sealing the collected product(s). Use of this port compromises the sterile fluid pathway.

1. Place a hermetic seal on the red-striped blood line tubing near the needle connector.
2. Seal or clamp the anticoagulant line tubing near the needle connector.

Warning! Failure to seal or clamp the anticoagulant and blood line tubing may result in dilution of the sample with anticoagulant. A diluted blood sample may cause inaccurate test results.

3. Using standard venipuncture materials, collect an adequate sample of blood for post-procedure testing from the injection port at the needle site. Haemonetics recommends discarding the first 3 to 5 ml from the tubing. The sample collected after discard is representative of the donor whole blood.

Completing the Procedure

1. Follow the procedure outlined in the section entitled "Post-procedure Sample Collection (Optional)" for obtaining an optional post-procedure sample.
2. Place a hermetic seal between the needle and the product.

Warning! Do not remove the needle before hermetically sealing the collected product(s). Removing the needle compromises the sterile fluid pathway.

3. Remove the venipuncture needle.
4. Apply a pressure dressing and release the donor according to standard operating procedures.
5. Remove any residual air from the platelet bag.

To remove air from platelet bag:

a. Gently roll the platelet bag containing the platelet concentrate from the bottom.
b. Open the White Valve and Green Valve manually.
c. Transfer air from the platelet bag to the air bag.
d. When all the air is expressed, allow the valves to close.

6. Obtain product sample.

To obtain a platelet product sample:

a. Hermetically seal the green-striped line at the T-connector and remove platelet bags from the disposable set.
b. Open the sample pouch and allow the fluid in the tubing between the sample pouch and the platelet bag to drain into the platelet bag. Open the slide clamp on the second platelet bag to help drain the tubing.

c. Close the slide clamps to both platelet bags. Manually mix the platelet product thoroughly with a back-and-forth motion for at least 30 seconds.

d. Open the slide clamp to the platelet bag, invert the bag so the ports are down, and allow the platelets to flow into the sample pouch. Fill the sample pouch completely.

e. Raise the sample pouch to allow the product in the sample pouch to drain back into the platelet bag.

f. Transfer a platelet sample from the platelet bag into the sample pouch. Stop when volume sufficient for sampling has been achieved. Invert the platelet bag to squeeze air into the sample pouch. Close the clamp on the sample pouch. Reclamp the line adjacent to the platelet bag.

g. Hermetically seal the sample pouch tubing and remove for a platelet count.

Warning! Any potential opening within the disposable set prior to the platelet concentrate being removed requires that the product storage life be reduced to 24 hours.

h. If the product yield exceeds the capacity of one platelet bag, hang the platelet bags port down with both clamps open to allow the platelet concentrate to flow between both platelet bags until an equal amount (approximately) of concentrate is in each bag.

i. The platelets are ready to be stored.

To remove air from the plasma bag:

a. Invert the plasma bag and hang it with ports up on the Weigher.

b. Remove the tubing from the Yellow Valve.

c. Manually open the White Valve and transfer the air from the plasma bag into the air bag.

d. Seal the plasma bag.

e. The plasma can now be removed from the disposable.

Warning! Prior to freezing the plasma, all air has to be removed from the plasma bag.

7. Remove disposable and dispose of in accordance with standard operating procedures.

Protocol

LEUKOCYTE MANAGEMENT SYSTEM

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Instructions for Use

Haemonetics offers three disposable kits with incorporated Pall Leukoreduction filters, LN 994CF, LN 994CF-CPP and LN 994F. The LN 994CF and LN 994CF-CPP disposables are designed for pre-storage filtration occurring continuously during the platelet collection procedure. The LN 994F disposable is designed for pre-storage filtration after completion of the procedure.

Setup and Filtration with LN 994CF, LN 994CF-CPP Disposable

Haemonetics recommends that the following procedural guidelines be followed to ensure a leukocyte-reduced product containing less than 1 x 10^5 white cells in at least 99% and less than 5 x 10^4 in at least 95% of all filtered Single Donor Platelet products collected with the LN 994CF or LN 994CF-CPP disposable. Double unit platelets collected in accordance with the following procedural guidelines are expected to contain a leukocyte-reduced product containing less than 1 x 10^6 white cells in the combined double unit platelet product in at least 97.8% (+/- 4.3%) of all products collected with the LN 994CF or LN 994CF-CPP disposable.

- There is no change to the priming or operation of the MCS+ when using the disposable kits with incorporated white blood cell filters. The only difference in the setup is the placement of the collection bags of the disposable.
- For collection of apheresis platelet products, the operator should target a platelet yield that has been validated to meet the institution's requirements for acceptable platelet products.

  Haemonetics recommends that the user conduct process validations to establish a Target Yield that accounts for product filtration, variability in splitting and subsequent product counting.
- Carefully follow the recommended procedure for filtering and sampling as outlined in this chapter.

Note: In the event of an RBC spill, manual intervention in the filtration process, or a volume processed greater than 5000 ml, Haemonetics recommends counting and verifying WBC contents prior to labeling the product as leukocyte-reduced.

Warning! If reverse flow of the filtered platelet product back through the leukocyte reduction filter has occurred, the platelet product should be discarded in accordance with your institution's standard operating procedures.

Disposable Setup (LN 994CF, LN 994CF-CPP)

The LN 994CF is identical to the LN 994 Single Donor Platelet Collection Set with the exception of the following additional components:

- Reservoir bag. During the procedure the collected platelets will be held until the product is filtered.
- The leukoreduction filter is in-line between the reservoir bag and the platelet storage bags.

Install the disposable in the same manner as the LN 994 disposable (as described in the "General" section of this manual), with the exception of the collection side of the harness from the green tubing side of the "T" connector. Install this portion of the disposable as follows:

1. Thread the green-striped tubing into the corresponding Green Valve.
2. Hang the reservoir bag with ports down on the small pole on the right-hand side of the MCS+. The chimney port (green-striped inlet line) should be facing away from the machine.
3. Hang the platelet bags with ports down on the same pole. The platelet bags should be located between the reservoir bag and the MCS+. (See Figure 1.)
4. Close the red slide clamp on the tubing between the filter and one of the platelet bags. Close the clamp at the sample pouch. Ensure that the clamp to one platelet bag remains open.
5. Allow the filter to hang naturally on the side of the machine.
6. Verify that the tubing on either side of the filter is not twisted or kinked.

Once this is complete, proceed with installation of the disposable according to the instructions for use as outlined in the "General" section of this manual.

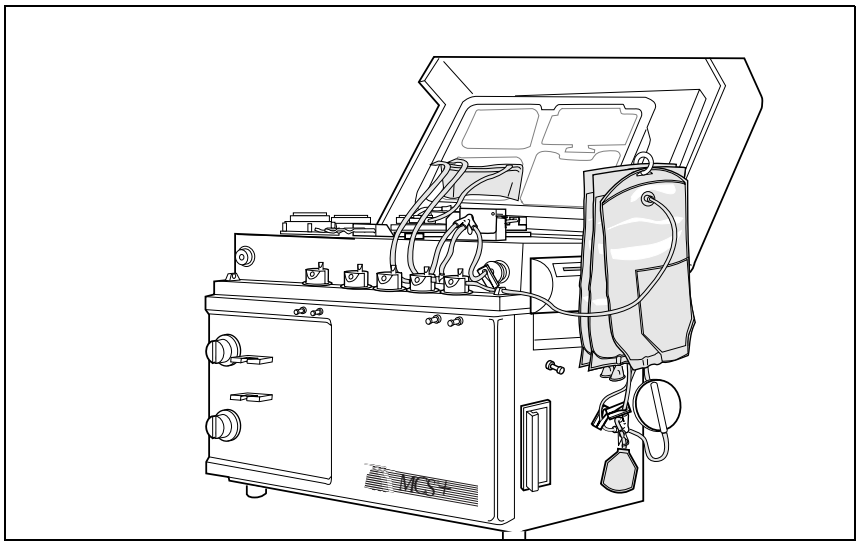

Figure 1, Installation of the LN 994CF disposable

Filtration Method

The platelet product will be filtered automatically during the platelet collection procedure.

1. After completion of the platelet collection procedure, remove the platelet bags from the pole and allow to hang down freely. Allow the reservoir bag to remain on the pole. The product remaining in the reservoir bag will flow through the filter into the platelet bag.
2. After filtration has been completed, hermetically seal the tubing between the leukoreduction filter and the “four-way Y” connector and remove the platelet bags from the disposable set.

Note: Allow the reservoir bag to completely empty before sealing the tubing. This also includes allowing the upstream side of the filter to drain as much of the product as possible.

3. Remove the disposable and dispose of in accordance with standard operating procedures.

Note: The approximate residual amount of blood in the collection set at the conclusion of a normal procedure is approximately 55 ml, of which approximately 45 ml is plasma.

Clean any spills immediately.

Sampling Method

For Single Platelet Products

1. Open the clamp on the sample pouch, allowing the fluid in the tubing between the "four-way Y" connector and the platelet bag to drain into the platelet bag.
2. Open the slide clamps to the platelet product bags. Invert the bag containing the platelets so the ports are down and allow the platelets to flow into the sample pouch. Fill the sample pouch completely.
3. Raise the sample pouch to allow the product in the sample pouch to drain back into the platelet bag.

Note: Filling the pouch completely, before taking only the necessary volume for sampling, washes any residual cells from the plastic surface and is an important step in ensuring sample accuracy.

4. Close the slide clamps to both platelet bags. Manually mix the platelet product thoroughly with a rocking back-and-forth motion for at least 30 seconds.
5. Express air from the platelet bag into the sample pouch. DO NOT PRESSURIZE THE SAMPLE POUCH. Some air may remain in the platelet product. Close the clamp on the sample pouch.
6. Open the clamp on the sample pouch line and next to the platelet bag. Allow the product in the platelet product bag to fill approximately 5" of the 14" tubing leading to the sample pouch, but do not allow the product to enter the sample pouch.
7. Hermetically seal the sample pouch tubing and remove for a platelet count.
8. Cut the sample pouch tubing and transfer sample into an EDTA tube.
9. Obtain the cell counts from the sample.
10. Obtain the platelet product volume:
    a. Place the platelet bags containing the filtered platelet product on a calibrated gram scale. Record the total weight.
    b. Subtract the tare weight from the total weight. This is the product weight.
    c. Divide the product weight by 1.026 g/ml. This is the product volume.
11. Calculate the total platelet product yield.
12. If the product yield exceeds the capacity of one platelet bag, hang the platelet bags ports down with both clamps open to allow the platelet concentrate to flow between both platelet bags until an (approximately) equal amount of concentrate is in each bag.
13. Hang the platelet bags with ports up to allow the platelet product that remains in the tubing between both platelet bags to flow into one of the platelet bags.

14. Label the platelet product per institution's policy.
15. The platelets are ready to be stored.

For Double Unit Platelet Products

1. Open the clamp on the sample pouch, allowing the fluid in the tubing between the "four-way Y" connector and the platelet bag to drain into the platelet bag.
2. Open the slide clamps to the platelet product bags. Invert the bag containing the platelets so the ports are down and flow the platelets into the sample pouch. Fill the sample pouch completely.
3. Raise the sample pouch to allow the product in the sample pouch to drain back into the platelet bag.

Note: Filling the pouch completely, before taking only the necessary volume for sampling, washes any residual cells from the plastic surface and is an important step in ensuring sample accuracy.

4. Open the clamp on the sample pouch line and next to the platelet bag. Allow the product in the platelet product bag to fill approximately 5″ of the 14″ tubing leading to the sample pouch but do not allow the product to enter the sample pouch.
5. Express air from the platelet bag into the sample pouch. DO NOT PRESSURIZE THE SAMPLE POUCH. Some air may remain in the platelet product. Close the clamp on the sample pouch.
6. Hermetically seal the sample pouch tubing and remove for a platelet count.
7. Cut the sample pouch tubing and transfer the pre-split sample into a dry EDTA tube.
8. Obtain the cell counts from the pre-split sample.
9. Obtain the platelet product volume:
    a. Place the platelet bags containing the filtered platelet product on a calibrated gram scale. Record the total weight.
    b. Subtract the tare weight from the total weight. This is the product weight.
    c. Divide the product weight by 1.026 g/ml. This is the product volume.
10. Calculate the total pre-split platelet product yield.

Warning! If the platelet yield exceeds the capacity of two platelet bags, additional platelet storage bags should be attached using a sterile connection device.

11. Close the slide clamps to both platelet bags. Manually mix the platelet product thoroughly with a rocking back-and-forth motion for at least 30 seconds.

12. Hang the platelet bags ports down. Open the clamps to one bag of each unit to allow the platelet concentrate to flow between both platelet bags until an (approximately) equal amount of concentrate is in each unit.

Note: To ensure that an equal split is achieved, steps 12 and 13 should be performed together.

13. Hang the platelet bags with ports up to allow the platelet product that remains in the tubing between both platelet bags to flow into one of the platelet bags. Close the clamp to each bag.

14. Using a calibrated gram scale, ensure that an equal split between both single donor platelet units is achieved. The estimated yield in each unit should be at least 3.0×10^{11} platelets. Otherwise, repeat steps 12 and 13 until each unit is expected to contain at least 3.0×10^{11} platelets.

15. Steps 15a through 15g describe an optional procedure to validate that the concentration in both units is equivalent.
    To obtain a sample from each individual unit:
    a. Using a tubing stripper, empty platelet product remaining in the 14″ tubing into the first platelet unit.
    b. Manually mix the platelet product thoroughly with a rocking back-and-forth motion for at least 30 seconds.
    c. Using a tubing stripper collect a platelet sample from the platelet unit into the 14″ tubing.
    d. Hermetically seal off a 5″ section of the 14″ tubing.
    e. Cut the 5″ tubing segment and transfer the sample into an EDTA tube.
    f. Obtain a cell count for the platelet unit.
    g. Repeat steps for second platelet unit.

16. Separate the two single donor platelets units. In case additional platelet bags have been attached, equalize the platelet product between the platelet bags and remove fluid from the tubing.

17. Obtain the platelet product volume for each product:
    a. Place the platelet bags containing the filtered platelet product on a calibrated gram scale. Record the total weight.
    b. Subtract the appropriate tare weight from the total weight. This is the product weight.
    c. Divide the product weight by 1.026 g/ml. This is the product volume.

18. Calculate the total pre-split platelet product yield in each platelet unit.

19. Label each platelet product per institution's policy.
20. The platelets are ready to be stored.

Setup and Filtration with the LN 994F Disposable

Haemonetics recommends that the following procedural guidelines are followed to ensure a leukocyte-reduced product containing less than 5×10^6 white cells in at least 95% of all filtered Single Donor Platelet products collected with the LN 994F disposable. The LN 994F disposable has not been validated for collection of leukocyte-reduced double platelet units.

The platelet product can be filtered immediately upon completion of the platelet collection procedure or up to one hour after collection. Filtration of the platelet product takes approximately 5 to 10 minutes.

- There is no need to change the priming or operating of the MCS+ to use the disposable with incorporated white blood cell filter. The only difference is in the setup of the collection bags of the disposable.
- Set the HaemoCalculator Target Yield to 4.0×10^{11}. This target should be adjusted as necessary based on site validation in order to account for product filtration.
- Do not process more than 4500 ml to achieve this target. (Processing higher volumes to obtain a 4.0×10^{11} platelet yield may result in increased white blood cell contamination).
- Do not remove the air from the reservoir bag prior to filtering. (Removal of air before filtration will prevent the bag from completely emptying during the filtration process and can result in the loss of some platelet product.)
- Carefully follow the recommended procedure for filtering and sampling as outlined in this chapter.
- In the event of an RBC spill, or a volume processed greater than 4500 ml, Haemonetics recommends counting and verifying WBC contents prior to labeling the product as leukocyte-reduced.

Disposable Setup – LN 994F

The disposable set is identical to the LN 994 Single Donor Platelet Collection Set with the exception of the following additional components:

- Reservoir bag. During the procedure, the collected platelets will be held in this bag until the product is filtered.
- The leukoreduction filter which is in-line between the reservoir bag and the platelet storage bags.

Install the disposable in the same manner as the Single Donor Platelet or Platelets and Plasma Protocol describes with the exception of the collection side of the harness from the green tubing side of the "T" connector. Install this portion of the disposable as follows:

1. Thread the green-striped tubing into the corresponding Green Valve.
2. Hang the platelet bags attached to the leukoreduction filter on the middle bag pin located on the right-hand side panel of the MCS+.
3. Hang the reservoir bag with ports up on the right bag pins located on the front panel of the MCS+.
4. Allow the filter to hang naturally on the side of the machine.
5. Close the red slide clamp on the tubing between the reservoir bag and the leukoreduction filter.
6. Close the three clamps on the tubing between the filter and both platelet bags and the sample pouch.

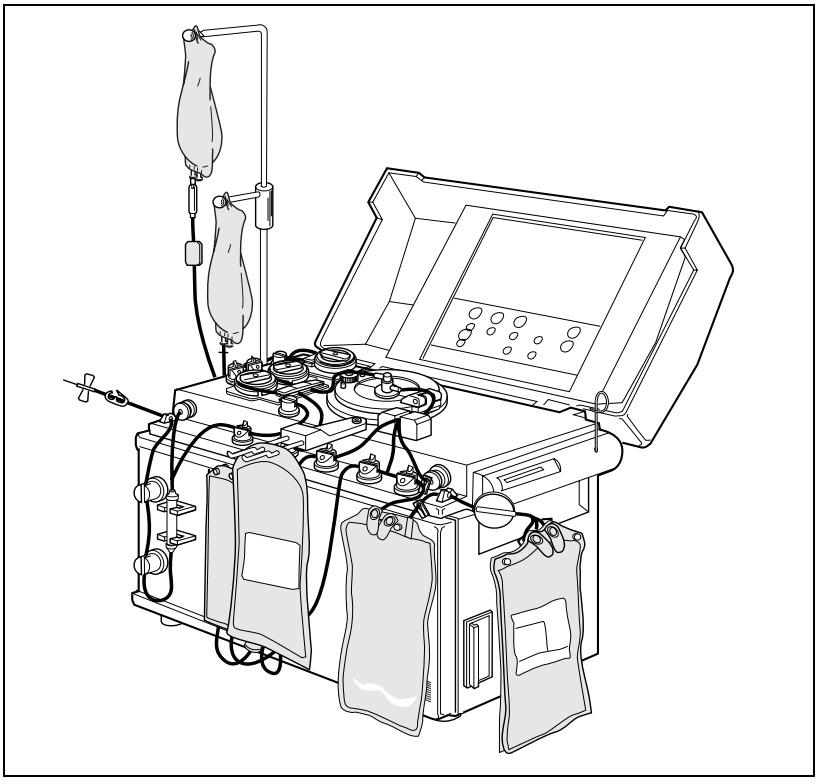

Figure 2, Installation of the LN 994F disposable

Once this is complete, proceed with installation of the disposable according to the instructions for use of the selected Platelet Protocol or Platelets and Plasma Protocol.

Filtration Method – LN 994F

The platelet product can be filtered immediately upon completion of the platelet collection procedure and up to one hour after collection. Filtration of the platelet product takes approximately 5 to 10 minutes.

Warning! DO NOT REMOVE THE AIR FROM THE RESERVOIR BAG! Removal of air from the reservoir bag before filtration will prevent the bag from completely emptying during the completion of the filtration process and can result in the loss of some platelet product.

1. Manually mix the contents of the reservoir bag for at least 30 seconds.

Warning! This mixing is very important for obtaining accurate sample measurements and for effective filtration.

2. To obtain a prefiltration sample, perform the following steps 2a through 2e. If no sample is necessary, advance to step 3.
   a. Manually open Green and White Valves and invert the platelet bag with ports down and allow the product to flow back into the tubing, filling approximately 5 to 10" in length. (Five inches of tubing equals approximately one ml of sample; take only the sample size necessary for your lab to measure the product.)
   b. Seal both ends of the "sample" tubing. Seal and separate the "sample" tubing from the disposable set. Cut the end of the "sample" tubing and drain the sample into an EDTA tube.

Note: The process of sealing and separating the "sample" tubing from the reservoir bag should follow the institution's standard operating procedures for separating platelet products from disposable sets (type and number of seals).

   c. Place the entire filter assembly on a calibrated gram scale (reservoir bag with product, filter, platelet bags, sample pouch, and tubing). Record the weight.
   d. Subtract the tare weight from the weight obtained in step 2c. This is the prefiltration product weight. Calculate the platelet concentration per your institution's standard operating procedures using this value.
   e. Advance to step 4.
3. If no prefiltration sample has been taken, seal and cut the tubing between the Green Valve and the top of the reservoir bag and advance to step 4. Follow your institution's policy for separating platelet products from disposable sets.
4. Hang the reservoir bag with ports down on an IV pole. Be sure the assembly is fully extended and hangs freely.
5. Open the red slide clamp on the tubing to one of the platelet bags.

6. Open the red slide clamp between the reservoir bag and the filter allowing the platelets to flow through the filter.

Warning! Do not stop or reverse flow at any time during the filtration process. Stopping or reversing the flow may cause the filter to become blocked.

Warning! Do not use any mechanical assistance for filtration process. Filtration must be by gravitation only to be effective.

7. After filtration has been completed, seal the tubing between the leukoreduction filter and the “four-way Y” connector. Separate the two sections.

Note: Allow the reservoir bag to completely empty before sealing the tubing. This also includes allowing the front side of the filter to drain as much of the product as possible.

8. Open the slide clamp on the sample pouch, allowing the fluid in the tubing between the ”four-way Y” connector and the platelet bag to drain into the platelet bag. Open the slide clamp on the second platelet bag to finish draining the tubing.
9. Express all air from the platelet bag into the sample pouch. Close the clamp on the sample pouch.
10. Close the slide clamps to both platelet bags. Gently mix the platelet product thoroughly for at least 30 seconds.
11. To take a post-filtration sample, follow steps 11a through 11e.
    a. Place the platelet bags containing the filtered platelet product on a scale. Record the weight.
    b. Subtract the tare weight from the weight obtained in step 11a. This is the post-filtration product weight.
    c. Open the slide clamp to the platelet product bag and open the sample pouch. Invert the bag containing the platelets so the ports are down and allow the platelets to flow into the sample pouch. Fill the sample pouch completely.
    d. Return the bag to the ports up position and allow the product in the sample pouch to drain back into the platelet product bag.
    e. Allow a minimum volume of platelet product to flow from the platelet storage bag into the sample pouch. Express air from the platelet bag into the sample pouch. Close the clamps on both. Only a minimal sample volume is needed for laboratory evaluations.

Note: Filling the sample pouch completely, before taking only the necessary volume for sampling, washes any residual cells from the plastic surface and is an important step in ensuring sample accuracy.

12. Hermetically seal the sample pouch tubing and remove the sample pouch.
13. Cut the sample pouch tubing and transfer the sample into an EDTA tube.
14. Obtain the cell counts from the sample.
15. Calculate the platelet concentration per institution's standard operating procedures.
16. Open both platelet bag clamps and invert the bags ports down to redistribute half of the platelet product into the second platelet product bag.
17. With ports up and both bags still open, the tubing will be empty; close clamps.
18. Platelets are now ready to be stored according to standard operating procedure.

Recommendations for Validation of Procedure and Counting Method

The institution should validate its own collection, filtration, and white cell counting procedures. Haemonetics has demonstrated that if the instructions as described in this chapter of the *MCS+ Platelet Protocols Manual* are followed, the user will be able to successfully collect leukocyte-reduced platelet products.

Haemonetics recommends that institutions validate their white cell counting methodology by following the recommended practices described in the May 29, 1996 Food and Drug Administration's "Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products" guidance document.

For questions or concerns about the validation of procedures, please contact Haemonetics at (800) 433-3431.